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(54) Title: SKIN CARE COMPOSITIONS CONTAINING SILICONE ELASTOMERS

(57) Abstract: The present invention relates to a topical skin care composition having improved aesthetics containing a skin care active wherein the skin care active is soluble in a tacky solvent and wherein the dermatologically acceptable delivery system contains a tacky solvent in combination with a silicone elastomer and a carrier for the elastomer. The present invention also relates to methods of using such compositions to regulate the condition of mammalian skin while retaining good aesthetics.

SKIN CARE COMPOSITIONS CONTAINING SILICONE ELASTOMERS

TECHNICAL FIELD

The present invention relates to topical skin care compositions containing silicone elastomers and methods of use thereof. Such compositions are useful for delivering skin care actives in products with consumer acceptable aesthetics.

BACKGROUND

Many personal care products currently available to consumers are directed primarily to improving the health and/or physical appearance of the skin and/or hair. Among the skin care products, many are directed to delaying, minimizing or even eliminating skin wrinkling and other histological changes typically associated with the aging of skin or environmental damage to human skin. Numerous compounds have been described in the art as being useful for regulating skin condition, including regulating fine lines, wrinkles and other forms of uneven or rough surface texture associated with aged or photodamaged skin.

Skin is subject to insults by many extrinsic and intrinsic factors. Extrinsic factors include ultraviolet radiation (e.g., from sun exposure), environmental pollution, wind, heat, low humidity, harsh surfactants, abrasives, and the like. Intrinsic factors include chronological aging and other biochemical changes from within the skin. Whether extrinsic or intrinsic, these factors result in visible signs of skin aging and environmental damage, such as wrinkling and other forms of roughness (including increased pore size, flaking and skin lines), and other histological changes associated with skin aging or damage. To many people, skin wrinkles are a reminder of the disappearance of youth. As a result, the elimination of wrinkles has become a booming business in youth-conscious societies. Treatments range from cosmetic creams and moisturizers to various forms of cosmetic surgery.

Extrinsic or intrinsic factors may result in the thinning and general degradation of the skin. For example, as the skin naturally ages, there is a reduction in the cells and blood vessels that supply the skin. There is also a flattening of the dermal-epidermal junction which results in weaker mechanical resistance of this junction. See, for example, Oikarinen, "The Aging of Skin:

Chronoaging Versus Photoaging," *Photodermatol. Photoimmunol. Photomed.*, vol. 7, pp. 3-4, 1990, which is incorporated by reference herein in its entirety.

One example of a cosmetic active that has been used to alleviate the signs of skin aging is niacinamide. Niacinamide is the physiologically active form of niacin. Niacin, also known as vitamin B_3, is the common name for nicotinic acid. Niacin and niacinamide (nicotinic acid amide, nicotinamide) function in the body as components of two coenzymes: nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Until recently, these vitamin B_3 compounds were used exclusively to treat niacin deficiency and pellegra.

Today, however, vitamin B_3 compounds are also used for topical application as skin care actives. British patent 1,370,236 and U.S. patent 4,096,240 disclose niacinamide applied topically to the skin to promote skin lightening. Similarly, niacinamide has been disclosed for numerous other skin benefits including regulation of oily skin and regulation of cellulite.

Unfortunately, many skin care actives such as niacinamide have poor solubility in conventional delivery systems. For instance, skin care compositions containing high concentrations of vitamin B_3 compounds tend to leave a visible white residue on the skin upon application. This residue apparently results from a "salting out" of the vitamin B_3 compound.

Based on the foregoing, there is a continuing need to formulate skin care compositions having improved delivery of skin care actives while maintaining good skin feel and aesthetics.

Surprisingly, it has now been found that compositions containing actives that require tacky solvents to insure solubility (especially when applied to skin) can be prepared that retain good aesthetics through the use of an improved delivery system.

None of the existing art provides all of the advantages and benefits of the present invention.

SUMMARY

The present invention relates to a topical skin care composition having improved aesthetics containing from about 0.0001% to about 40%, by weight of the composition, of a skin care active wherein the skin care active is soluble in a tacky solvent, and a dermatologically acceptable delivery system, wherein the delivery system contains from about 1% to about 60%, by weight of the composition, of a tacky solvent; from about 0.1% to about 30% of a silicone elastomer; and from about 1% to about 80% of a carrier for the elastomer; wherein the mixture of the tacky solvent and the skin care active has a sensory tactile perception rating of greater than 4.5 and the resulting composition has a sensory tactile perception rating of less than 4.5.

The present invention also relates to methods of using such compositions to regulate the condition of mammalian skin. Said methods generally contain the step of topically applying a safe and effective amount of the composition to the skin of a mammal needing such treatment.

These and other features, aspects, and advantages of the present invention will become evident to those skilled in the art from a reading of the present disclosure.

DETAILED DESCRIPTION

While the specification concludes with the claims particularly pointing and distinctly claiming the invention, it is believed that the present invention will be better understood from the following description.

All percentages and ratios used herein are by weight of the total composition and all measurements made are at 25°C, unless otherwise designated.

As used herein, the "skin care products" are those used to treat or care for, or somehow moisturize, improve, or clean the skin. Products contemplated by the phrase "skin care products" include, but are not limited to moisturizers, personal cleansing products, occlusive drug delivery patches, nail polish, powders, wipes, hair conditioners, skin treatment emulsions, shaving creams and the like.

The term "ambient conditions" as used herein refers to surrounding conditions under about one atmosphere of pressure, at about 50% relative humidity, and at about 25°C. unless otherwise specified.

The compositions of the present invention can include, consist essentially of, or consist of, the components of the present invention as well as other ingredients described herein. As used herein, "consisting essentially of" means that the composition or component may include additional ingredients, but only if the additional ingredients do not materially alter the basic and novel characteristics of the claimed compositions or methods.

All percentages, parts and ratios are based upon the total weight of the skin care compositions of the present invention, unless otherwise specified. All such weights as they pertain to listed ingredients are based on the active level and, therefore, do not include carriers or by-products that may be included in commercially available materials, unless otherwise specified.

All publications cited herein are hereby incorporated by reference in their entirety.

The term "keratinous tissue," as used herein, refers to keratin-containing layers disposed as the outermost protective covering of mammals (e.g., humans, dogs, cats, etc.) which includes, but is not limited to, skin, lips, hair, toenails, fingernails, cuticles, hooves, etc.

The term "dermatologically-acceptable," as used herein, means that the compositions or components thereof so described are suitable for use in contact with mammalian keratinous tissue without undue toxicity, incompatibility, instability, allergic response, and the like.

The term "safe and effective amount" as used herein means an amount of a compound or composition sufficient to significantly induce a positive benefit, preferably a positive keratinous tissue appearance or feel benefit, or positive hair appearance or feel benefit, including independently or in combinations the benefits disclosed herein, but low enough to avoid serious side effects, i.e., to provide a reasonable benefit to risk ratio, within the scope of sound judgment of the skilled artisan.

The term "sagging" as used herein means the laxity, slackness, or the like condition of skin that occurs as a result of loss of, damage to, alterations to, and/or abnormalities in dermal elastin.

The terms "smoothing" and "softening" as used herein mean altering the surface of the keratinous tissue such that its tactile feel is improved.

"Signs of skin aging" include, but are not limited to, all outward visibly and tactilely perceptible manifestations as well as any other macro or micro effects due to skin aging. Such signs may be induced or caused by intrinsic factors or extrinsic factors, e.g., chronological aging and/or environmental damage. These signs may result from processes which include, but are not limited to, the development of textural discontinuities such as wrinkles and coarse deep wrinkles, skin lines, crevices, bumps, large pores (e.g., associated with adnexal structures such as sweat gland ducts, sebaceous glands, or hair follicles), or unevenness or roughness, loss of skin elasticity (loss and/or inactivation of functional skin elastin), sagging (including puffiness in the eye area and jowls), loss of skin firmness, loss of skin tightness, loss of skin recoil from deformation, discoloration (including undereye circles), blotching, sallowness, hyperpigmented skin regions such as age spots and freckles, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown, and other histological changes in the stratum corneum, dermis, epidermis, the skin vascular system (e.g., telangiectasia or spider vessels), and underlying tissues, especially those proximate to the skin.

It is desirable to have one or more skin care actives at high levels for skin care benefits such as regulating the condition of skin. However, when high levels of skin care actives are used in traditional skin care products, there is a downside. For example, residue caused by "salting out" of niacinamide produces an undesirable whitening effect on the skin.

The use of a non-volatile solvent such as glycerin allows the skin care active to remain solubilized on the skin and therefore reducing the visible residue (i.e. whitening) on the skin. However, using such solvents to reduce the visible residue causes yet another aesthetic problem, a sticky feel on the skin.

Silicone elastomers are known in the art as useful components in skin care compositions. Such silicone elastomers are known to reduce the tackiness/stickiness associated with skin conditioning agents, including glycerin.

It has now surprisingly been found that by adding a silicone elastomer to a composition having high levels of skin care actives and a nonvolatile solvent, such composition has acceptable aesthetics including reduced visible residue and reduced stickiness.

The present invention is also useful for therapeutically regulating visible and/or tactile discontinuities in mammalian skin, including discontinuities in skin texture and color. For example, the apparent diameter of pores decreases, the apparent height of tissue immediately proximate to pore openings approaches that of the interadnexal skin, the skin tone/color becomes more uniform, and/or the length, depth, and/or other dimension of lines and/or wrinkles are decreased.

The compositions of the present invention are also useful for regulating the condition of skin and especially for regulating keratinous tissue condition. Regulation of skin condition, namely mammalian and in particular human skin condition, is often required due to conditions which may be induced or caused by factors internal and/or external to the body. Examples include, environmental damage, radiation exposure (including ultraviolet radiation), chronological aging, menopausal status (e.g., post-menopausal changes in skin), stress, diseases, etc. For instance, "regulating skin condition" includes prophylactically regulating and/or therapeutically regulating skin condition, and may involve one or more of the following benefits: thickening of skin (i.e., building the epidermis and/or dermis and/or sub-dermal (e.g., subcutaneous fat or muscle) layers of the skin and where applicable the keratinous layers of the nail and hair shaft) to reduce skin atrophy, increasing the convolution of the dermal-epidermal border (also known as the rete ridges), preventing loss of skin elasticity (loss, damage and/or inactivation of functional skin elastin) such as elastosis, sagging, loss of skin recoil from deformation; non-melanin skin discoloration such as under eye circles, blotching (e.g., uneven red coloration due to, e.g., rosacea) (hereinafter referred to as "red blotchiness"), sallowness (pale color), discoloration caused by telangiectasia or spider vessels.

As used herein, prophylactically regulating skin condition includes delaying, minimizing and/or preventing visible and/or tactile discontinuities in skin (e.g., texture irregularities in the skin which may be detected visually or by feel).

As used herein, therapeutically regulating skin condition includes ameliorating, e.g., diminishing, minimizing and/or effacing, discontinuities in skin.

The compositions of the present invention provide additional benefits, including stability, absence of significant (consumer-unacceptable) skin irritation and good aesthetics.

The compositions of the present invention contain a skin care active, a tacky solvent, a silicone elastomer, and a solvent for the silicone elastomer.

The compositions herein may also include a wide variety of other ingredients. The compositions of the present invention, are described in detail hereinafter.

I. Skin Care Active

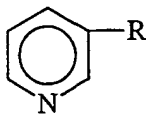
The topical compositions of the present invention also include from about 0.0001% to about 40% of skin care active that is soluble in a tacky solvent.

By "soluble in a tacky solvent" is meant those skin care actives that may be incorporated into the tacky solvent component in order to solubilize or disperse the skin care active. Furthermore, if the tacky solvent is not used to solubilize/disperse these actives, the active precipitates out onto the skin after application of the formulation onto the skin. The soluble skin care active component may be selected from niacinamide, magnesium ascorbyl phosphate, zeolites, peptides, sunscreen actives, and mixtures thereof.

Niacinamide

The skin care active for use herein is preferably selected from niacinamide (or another solid at ambient temperature vitamin B_3 compound that is soluble in a tacky solvent). The present invention preferably includes from above 3.0% to about 40%, more preferably from about 5% to about 30%, even more preferably from about 5% to about 20% of a vitamin B_3 compound.

As used herein, "niacinamide" means a compound having the formula:



wherein R is - $CONH_2$.

The skin care active that is soluble in a tacky solvent may also be selected from one or more vitamin B_3 compounds other than niacinamide provided that the vitamin B_3 compound is a solid at ambient temperature and is soluble in the tacky solvent component.

The niacinamide may be included as the substantially pure material, or as an extract obtained by suitable physical and/or chemical isolation from natural (e.g., plant) sources. The vitamin B_3 compound is preferably substantially pure, more preferably essentially pure.

Magnesium Ascorbyl Phosphate

Magnesium ascorbyl phosphate is a stable form of vitamin C. In-vivo, it is converted to Vitamin C. It is soluble and stable in a variety of solvents including water, propylene glycol, 1,3-butylene glycol, maltitol, and glycerin. Unlike vitamin C, it is percutaneously absorbed into the skin. Magnesium ascorbyl phosphate is commercially available from Barnet Products Corp. as NIKKOL VC-PMG.

Zeolites

Zeolites are naturally hydrated silicate of aluminum and either sodium or calcium or both, of the type Na2O•Al2O3•xSiO2•xH2O. Both natural and synthetic zeolites may be used herein.

Natural zeolites suitable for use herein include analcite, chabazite, heulandite, natrolite, stilbite, and thomosonite. Synthetic zeolites suitable for use herein include those made by the gel process (sodium silicate and alumina) or a clay process (kaolin), which forms a matrix to which the zeolite is added. Preferred zeolites are sodium silicoaluminates available from UOP Molecular Sieves, Molecular Sieve Type 13X, Valfor Zeolite Na-A from PQ Corporation and Zeolex 7, 35 and 23A from Huber.

Peptides

Peptides, including but not limited to, di-, tri-, tetra-, and pentapeptides and derivatives thereof, may be included in the compositions of the present invention in amounts that are safe and effective. As used herein, "peptides" refers to both the naturally occurring peptides and synthesized peptides. Also useful herein are naturally occurring and commercially available compositions that contain peptides.

Suitable dipeptides for use herein include Carnosine® (beta-ala-his). Suitable tripeptides for use herein include, gly-his-lys, arg-lys-arg, his-gly-gly. Preferred tripeptides and derivatives thereof include palmitoyl-gly-his-lys, which may be purchased as Biopeptide CL® (100ppm of palmitoyl-gly-his-lys commercially available from Sederma, France); Peptide CK (arg-lys-arg); PEPTIDE CK+ (ac-arg-lys-arg-NH_2); and a copper derivative of his-gly-gly sold commercially as IAMIN, from Sigma (St. Louis, Missouri). Tetrapeptides and pentapeptides are also suitable for use herein. A preferred commercially available pentapeptide derivative composition is palmitoyl-lys-thr-thr-lys-ser (commercially available from Sederma France).

When included in the present compositions, peptides are preferably included in amounts of from about $1x10^{-6}$% to about 10%, more preferably from about $1x10^{-6}$% to about 0.1%, even more preferably from about $1x10^{-5}$% to about 0.01%, by weight of the composition. In certain compositions where the peptide is Carnosine®, the compositions preferably contain from about 0.1% to about 5%, by weight of the composition, of such peptides. In other embodiments wherein the peptide or peptide-containing composition palmitoyl-lys-thr-thr-lys-ser and/or Biopeptide CL® are included, the compositions preferably contain from about 0.0001% to about 10%, of palmitoyl-lys-thr-thr-lys-ser and/or Biopeptide CL® peptide-containing composition.

Sunscreen Actives

The solvent soluble skin care active may also be a sunscreen active that is solid at ambient temperature and is soluble and/or dispersible in the tacky solvent component. Non-limiting examples of such sunscreens include 2-Phenylbenzimidazole-5-sulphonic acid salts, Benzophenone-4, Benzylidene camphor sulfonic acid, DEA-Methoxycinnamate, TEA-Salicylate, Salts of Terephthalylidene Dicamphor sulfonic acid, and mixtures thereof.

a) 2-Phenylbenzimidazole-5-sulphonic acid salts

2-Phenylbenzimidazole-5-sulphonic acid salts are sunscreens that are soluble in water or polyhydric alcohols such as glycerin. The salts, sodium, potassium, triethanolamine are prepared in-situ from the corresponding bases. 2-Phenylbenzimidazole-5-sulphonic acid is commercially available from E. Merck (EUSOLEX 232), Roche (PARSOL HS) and Haarmann & Reimer (Neo Heliopan Type Hydro).

b) Benzophenone-4

Benzophenone-4 (Sulisobenzone) is a water or polyhydric alcohol soluble sunscreen. It is commercially available from BASF as Uvinol MS-40.

c) Benzylidene camphor sulfonic acid

Benzylidene camphor sulfonic acid is a water or polyhydric alcohol soluble sunscreen commercially available from Chimex as MEXORYL SL.

d) DEA-Methoxycinnamate

DEA-Methoxycinnamate is a water or polyhydric alcohol soluble derivative 4-Methoxycinnamic acid. It is commercially available from Nipa Hardwicke as NIPASORB D.

e) TEA-Salicylate

TEA-Salicylate (triethanolamine salicylate) is a water or polyhydric alcohol soluble derivative of Salicylic acid. It is commercially available from Haarmann & Reimer as NEO HELIOPAN TYPE TS and Kato Worldwide Ltd. as KATOSCREEN TES.

f) Salts of Terephthalylidene Dicamphor sulfonic acid

In-situ formation of salts of Terephthalylidene dicamphor sulfonic acid are soluble in water and polyhydric alcohols. These sunscreen actives are also known as 3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2oxo-bicyclo-(2.2.1) hept-1-ylmethanesulphonic acid. A commercially available salt of terephthalylidene dicamphor sulfonic acid is available from Chimex as MEXORYL SX.

II. Delivery System

The compositions of the present invention include an improved delivery system. The improved delivery system is a dermatologically acceptable delivery system. The phrase "dermatologically-acceptable delivery system," as used herein, means that the delivery system is suitable for topical application to the skin, has good aesthetic properties, is compatible with the skin care active(s) of the present invention and any other components, and will not cause any untoward safety or toxicity concerns.

A. Tacky Solvent

The topical compositions of the present invention include from about 1% to about 60%, by weight of the composition, of a tacky solvent. Tacky solvents are those solvents inherently having a tensile stress of greater than the tensile stress of petrolatum. The determination of tensile stress is known in the art and may be determined objectively by using the method described by Zeidler in Journal Seifen, Ole, Fette, Wache, 118 (1992) 1001, herein incorporated by reference.

Preferably, the composition includes from about 2% to about 50%, more preferably from about 5% to about 40%, by weight of the composition, of the tacky solvent.

Suitable tacky solvents for use herein include polyhydric alcohols such as polyalkylene glycols. Preferred for use herein are alkylene polyols and their derivatives. Examples of polyhydric alcohols useful herein include propylene glycol, dipropylene glycol, polypropylene glycol, polyethylene glycol, sorbitol, hydroxypropyl sorbitol, hexylene glycol, 1,3-butylene glycol, 1,2,6-hexenetriol, glycerin, ethoxylated glycerin, propoxylated glycerin, butanetriol, and mixtures thereof. A preferred polyhydric alcohol for use herein is glycerin.

Glycerin, also known in the art as "glycerol" or "glycyl alcohol" is a trihyric (polyhydric) alcohol according to the following formula:

CH2—OH
|
CH—OH

|
CH2—OH

The tacky solvents for use herein may be derived from any traditional means of manufacture and methods of purification.

B.. Silicone Elastomer

The compositions of the present invention also include from about 0.1% to about 30%, by weight of the composition, of a silicone elastomer component. Preferably, the composition includes from about 1% to about 20%, more preferably from about 2% to about 10% , by weight of the composition, of the silicone elastomer component.

Suitable for use herein are silicone elastomers which can be emulsifying or non-emulsifying crosslinked siloxane elastomers or mixtures thereof. No specific restriction exists as to the type of curable organopolysiloxane composition which can serve as starting material for the crosslinked organopolysiloxane elastomer. Examples in this respect are addition reaction-curing organopolysiloxane compositions which cure under platinum metal catalysis by the addition reaction between SiH-containing diorganopolysiloxane and organopolysiloxane having silicon-bonded vinyl groups; condensation-curing organopolysiloxane compositions which cure in the presence of an organotin compound by a dehydrogenation reaction between hydroxyl-terminated diorganopolysiloxane and SiH-containing diorganopolysiloxane; condensation-curing organopolysiloxane compositions which cure in the presence of an organotin compound or a titanate ester, by a condensation reaction between an hydroxyl-terminated diorganopolysiloxane and a hydrolyzable organosilane (this condensation reaction is exemplified by dehydration, alcohol-liberating, oxime-liberating, amine-liberating, amide-liberating, carboxyl-liberating, and ketone-liberating reactions); peroxide-curing organopolysiloxane compositions which thermally cure in the presence of an organoperoxide catalyst; and organopolysiloxane compositions which are cured by high-energy radiation, such as by gamma-rays, ultraviolet radiation, or electron beams.

Addition reaction-curing organopolysiloxane compositions are preferred for their rapid curing rates and excellent uniformity of curing. A particularly preferred addition reaction-curing organopolysiloxane composition is prepared from:

(A) an organopolysiloxane having at least 2 lower alkenyl groups in each molecule;

(B) an organopolysiloxane having at least 2 silicon-bonded hydrogen atoms in each molecule; and

(C) a platinum-type catalyst.

With regard to the above, component (A) is the basic component of the silicone elastomer-generating organopolysiloxane, and curing proceeds by the addition reaction of this component with component (B) under catalysis by component (C). This component (A) must contain at least 2 silicon-bonded lower alkenyl groups in each molecule; an excellent cured product will not be obtained at few than two lower alkenyl groups because a network structure will not be formed. Said lower alkenyl groups are exemplified by vinyl, allyl, and propenyl. While the lower alkenyl groups can be present at any position in the molecular, their presence at the molecular terminals is preferred. The molecular structure of this component may be straight chain, branched straight chain, cyclic, or network, but a straight chain, possibly slightly branched, is preferred. The molecular weight of the component is not specifically restricted, and thus the viscosity may range from low viscosity liquids to very high viscosity gums. In order for the cured product to be obtained in the form of the rubbery elastomer, it is preferred that the viscosity at 25 degrees Centigrade be at least 100 centistokes. These organopolysiloxanes are exemplified by methylvinylsiloxanes, methylvinylsiloxane-dimethylsiloxane copolymers, dimethylvinylsiloxy-terminated dimethylpolysiloxanes, dimethylvinylsiloxy-terminated dimethylsiloxane-methylphenylsiloxane copolymers, dimethylvinylsiloxy-terminated dimethylsiloxane-diphenylsiloxane-methylvinylsiloxane copolymers, trimethylsiloxy-terminated dimethylsiloxane-methylvinylsiloxane copolymers, trimethylsiloxy-terminated dimethylsiloxane-methylphenylsiloxane-methylvinylsiloxane copolymers, dimethylvinylsiloxy-terminated methyl(3,3,3-trifluoropropyl) polysiloxanes, and dimethylvinylsiloxy-terminated dimethylsiloxane-methyl(3,3,-trifluoropropyl)siloxane copolymers.

Component (B) is an organopolysiloxane having at least 2 silicon-bonded hydrogen atoms in each molecule and is a crosslinker for component (A). Curing proceeds by the addition reaction of the silicon-bonded hydrogen atoms in this component with the lower alkenyl groups in component (A) under catalysis by component (C). This component (B) must contain at least 2 silicon-bonded hydrogen atoms in each molecule in order to function as a crosslinker. Furthermore, the sum of the number of alkenyl groups in each molecule of component (A) and the number of silicon-bonded hydrogen atoms in each molecule of component (B) is to be at least 5. Values below 5 should be avoided because a network structure is then essentially not formed.

No specific restriction exists on the molecular structure of this component, and it may be any of straight chain, branch-containing straight chain, cyclic, etc. The molecular weight of this component is not specifically restricted, but it is preferred that the viscosity at 25 degrees

Centigrade be 1 to 50,000 centistokes in order to obtain good miscibility with component (A). It is preferred that this component be added in a quantity such that the molar ratio between the total quantity of silicon-bonded hydrogen atoms in the instant component and the total quantity of all lower alkenyl groups in component (A) falls within the range of (1.5:1) to (20:1). It is difficult to obtain good curing properties when this molar ratio falls below 0.5:1. When (20:1) is exceeded, there is a tendency for the hardness to increase to high levels when the cured product is heated. Furthermore, when an organosiloxane containing substantial alkenyl is supplementarily added for the purpose of; for example, reinforcement, it is preferred that a supplemental addition of the instant SiH-containing component be made in a quantity offsetting these alkenyl groups. This component is concretely exemplified by trimethylsiloxy-terminated methylhydrogenpolysiloxanes, trimethylsiloxy-terminated dimethylsiloxane-methylhydrogensiloxane copolymers, and dimethylsiloxane-methylhydrogen-siloxane cyclic copolymers.

Component (C) is a catalyst of the addition reaction of silicon-bonded hydrogen atoms and alkenyl groups, and is concretely exemplified by chloroplatinic acid, possibly dissolved in an alcohol or ketone and this solution optionally aged, chloroplatinic acid-olefin complexes, chloroplatinic acid-alkenylsiloxane complexes, chloroplatinic acid-diketone complexes, platinum black, and carrier-supported platinum.

Component C is added preferably at 0.1 to 1,000 weight parts, and more preferably at 1 to 100 weight parts, as platinum-type metal proper per 1,000,000 weight parts of the total quantity of components (A) plus (B). Other organic groups which may be bonded to silicon in the organopolysiloxane forming the basis for the above-described curable organopolysiloxane compositions are, for example, alkyl groups such as methyl, ethyl, propyl, butyl, and octyl; substituted alkyl groups such as 2-phenylethyl, 2-phenylpropyl, and 3,3,3-trifluoropropyl; aryl groups such as phenyl, tolyl, and xylyl; substituted aryl groups such as phenylethyl; and monovalent hydrocarbon groups substituted by, for example, the epoxy group, the carboxylate ester group, the mercapto group, etc.

Examples of the production of the organopolysiloxane elastomer powder are as follows: an organopolysiloxane composition as described above (additional-curable, condensation-curable, or peroxide-curable) is mixed with water in the presence of a surfactant (nonionic, anionic, cationic, or amphoteric), and, after mixing to homogeneity in a homomixer, colloid mill, homogenizer, propeller mixer, etc., this is cured by discharge into hot water (temperature at least 50 degrees Centigrade) and is then dried; the organopolysiloxane composition (addition-curable,

condensation-curable, or peroxide-curable) is cured by spraying it directly into a heated current; the powder is obtained by curing a radiation-curable organopolysiloxane composition by spraying it under high energy radiation; the organopolysiloxane composition (addition-curable, condensation-curable, peroxide-curable) or high energy-curable organopolysiloxane composition is cured, the latter by high energy radiation, and the product is then pulverized using a known pulverizer such as, for example, a ball mill, atomizer, kneader, roll mill, etc., to thereby form the powder.

The compositions of the present invention may include an emulsifying crosslinked organopolysiloxane elastomer, a non-emulsifying crosslinked organopolysiloxane elastomer, or a mixture thereof. The term "non-emulsifying," as used herein, defines crosslinked organopolysiloxane elastomers from which polyoxyalkylene units are absent. The term "emulsifying," as used herein, means crosslinked organopolysiloxane elastomers having at least one polyoxyalkylene (e.g., polyoxyethylene or polyoxypropylene) unit. Preferred emulsifying elastomers herein include polyoxyalkylene modified elastomers formed from divinyl compounds, particularly siloxane polymers with at least two free vinyl groups, reacting with Si-H linkages on a polysiloxane backbone. Preferably, the elastomers are dimethyl polysiloxanes crosslinked by Si-H sites on a molecularly spherical MQ resin. Emulsifying crosslinked organopolysiloxane elastomer can notably be chosen from the crosslinked polymers described in US Patents 5,412,004 (issued 5/2/95) ; 5,837,793 (issued 11/17/98); and 5,811,487 (issued 9/22/98), all of which are herein incorporated by reference in their entirety. In addition, an emulsifying elastomer comprised of dimethicone copolyol crosspolymer (and) dimethicone is available from Shin Etsu under the tradename KSG-21.

The silicone elastomers of the present invention may be further processed by subjecting them to a high shear (approximately 5,000 psi) treatment in the presence of a solvent for the silicone elastomer via a Sonolator with or without recycling in from 1 to 60 passes in order to result in a particular average particle size of silicone elastomer. Less than 10 passes results in an average particle size ranging from about 20 to 200 microns. From 10 to 60 passes results in an average particle size of less than 20 microns as measured by the Horiba LA-910. As used herein, the term "particle size" of the elastomer represents the elastomer particle size in its swelled state. By "swelled," as used herein, means the that the elastomer particles have extended beyond their normal size and shape by virtue of their absorption of the solvent compound.

Advantageously, the non-emulsifying elastomers are dimethicone/vinyl dimethicone crosspolymers. Such dimethicone/vinyl dimethicone crosspolymers are supplied by a variety of

suppliers including Dow Corning (DC 9040 and DC 9041), General Electric (SFE 839), Shin Etsu (KSG-15, 16, 18 [dimethicone/phenyl vinyl dimethicone crosspolymer]), and Grant Industries (GRANSIL™ line of elastomers). Cross-linked organopolysiloxane elastomers useful in the present invention and processes for making them are further described in U.S. Patent 4,970,252 to Sakuta, et al., issued November 13, 1990; U.S. Patent 5,760,116 to Kilgour, et al., issued June 2, 1998; U.S. Patent 5,654,362 to Schulz, Jr., et al. issued August 5, 1997, all of which are herein incorporated by reference. Additional crosslinked organopolysiloxane elastomers useful in the present invention are disclosed in Japanese Patent Application JP 61-18708, assigned to Pola Kasei Kogyo KK.

Commercially available elastomers preferred for use herein are Dow Corning's 9040 silicone elastomer blend, Shin Etsu's KSG-21, and mixtures thereof

C. **Carrier for Elastomer**

The topical compositions of the present invention include from about 1% to about 80%, by weight of the composition, of a suitable carrier for the for the crosslinked organopolysiloxane elastomer component described above. The carrier, when combined with the cross-linked organopolysiloxane elastomer particles of the present invention, serves to suspend and swell the elastomer particles to provide an elastic, gel-like network or matrix. The carrier for the cross-linked siloxane elastomer is liquid under ambient conditions, and preferably has a low viscosity to provide for improved spreading on the skin.

Concentrations of the carrier in the cosmetic compositions of the present invention will vary primarily with the type and amount of carrier and the cross-linked siloxane elastomer employed. Preferred concentrations of the carrier are from about 5% to about 50%, more preferably from about 5% to about 40%, by weight of the composition.

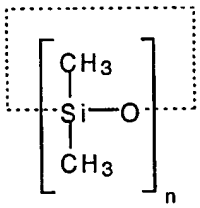
The carrier for the cross-linked siloxane elastomer includes one or more liquid carriers suitable for topical application to human skin. These liquid carriers may be organic, silicone-containing or fluorine-containing, volatile or non-volatile, polar or non-polar, provided that the liquid carrier forms a solution or other homogenous liquid or liquid dispersion with the selected cross-linked siloxane elastomer at the selected siloxane elastomer concentration at a temperature of from about 28° C. to about 250° C., preferably from about 28° C. to about 100° C., preferably from about 28° C. to about 78° C. The carrier for the cross-linked siloxane elastomer preferably has a solubility parameter of from about 3 to about 13 $(cal/cm^3)^{0.5}$, more preferably from about 5 to about 11 $(cal/cm^3)^{0.5}$, most preferably from about 5 to about 9 $(cal/cm^3)^{0.5}$. Solubility parameters for the liquid carriers or other materials, and means for determining such parameters,

are well known in the chemical arts. A description of solubility parameters and means for determining them are described by C. D. Vaughan, "Solubility Effects in Product, Package, Penetration and Preservation" 103 Cosmetics and Toiletries 47-69, October 1988; and C. D. Vaughan, "Using Solubility Parameters in Cosmetics Formulation", 36 J. Soc. Cosmetic Chemists 319-333, September/October, 1988, which articles are incorporated herein by reference.

The carrier preferably includes volatile, non-polar oils; non-volatile, relatively polar oils; non-volatile, non-polar oils; and non-volatile paraffinic hydrocarbon oils; each discussed more fully hereinafter. The term "non-volatile" as used herein refers to materials which exhibit a vapor pressure of no more than about 0.2 mm Hg at 25° C. at one atmosphere and/or to materials which have a boiling point at one atmosphere of at least about 300° C. The term "volatile" as used herein refers to all materials which are not "non-volatile" as previously defined herein. The phrase "relatively polar" as used herein means more polar than another material in terms of solubility parameter; i.e., the higher the solubility parameter the more polar the liquid. The term "non-polar" typically means that the material has a solubility parameter below about 6.5 $(cal/cm^3)^{0.5}$.

1. Non-polar, Volatile Oils

The non-polar, volatile oil tends to impart highly desirable aesthetic properties to the compositions of the present invention. Consequently, the non-polar, volatile oils are preferably utilized at a fairly high level. Non-polar, volatile oils particularly useful in the present invention are silicone oils; hydrocarbons; and mixtures thereof. Such non-polar, volatile oils are disclosed, for example, in Cosmetics, Science, and Technology, Vol. 1, 27-104 edited by Balsam and Sagarin, 1972. The non-polar, volatile oils useful in the present invention may be either saturated or unsaturated, have an aliphatic character and be straight or branched chained or contain alicyclic or aromatic rings. Examples of preferred non-polar, volatile hydrocarbons include polydecanes such as isododecane and isodecane (e.g., Permethyl-99A which is available from Presperse Inc.) and the C7 -C8 through C12 -C15 isoparaffins (such as the Isopar Series available from Exxon Chemicals). Non-polar, volatile liquid silicone oils are disclosed in U.S. Patent 4,781,917 issued to Luebbe et al. on Nov. 1, 1988, herein incorporated by reference in its entirety. Additionally, a description of various volatile silicones materials is found in Todd et al., "Volatile Silicone Fluids for Cosmetics", Cosmetics and Toiletries, 91:27-32 (1976), herein incorporated by reference in its entirety. Particularly preferred volatile silicone oils are selected from cyclic volatile silicones corresponding to the formula:



wherein n is from about 3 to about 7; and linear volatile silicones corresponding to the formula:

$$(CH_3)_3\ Si\text{--}O\text{--}[Si(CH_3)_2\text{-}O]_m\ \text{--}Si(CH_3)_3$$

wherein m is from about 1 to about 7. Linear volatile silicones generally have a viscosity of less than about 5 centistokes at 25° C., whereas the cyclic silicones have viscosities of less than about 10 centistokes at 25° C. Highly preferred examples of volatile silicone oils include cyclomethicones of varying viscosities, e.g., Dow Corning 200, Dow Corning 244, Dow Corning 245, Dow Corning 344, and Dow Corning 345, (commercially available from Dow Corning Corp.); SF-1204 and SF-1202 Silicone Fluids (commercially available from G.E. Silicones), GE 7207 and 7158 (commercially available from General Electric Co.); and SWS-03314 (commercially available from SWS Silicones Corp.).

2. Relatively Polar, Non-volatile oils

The non-volatile oil is "relatively polar" as compared to the non-polar, volatile oil discussed above. Therefore, the non-volatile co-carrier is more polar (i.e., has a higher solubility parameter) than at least one of the non-polar, volatile oils. Relatively polar, non-volatile oils potentially useful in the present invention are disclosed, for example, in Cosmetics, Science, and Technology, Vol. 1, 27-104 edited by Balsam and Sagarin, 1972; U.S. Patents 4,202,879 issued to Shelton on May 13, 1980; and 4,816,261 issued to Luebbe et al. on Mar. 28, 1989, all of which are herein incorporated by reference in their entirety. Relatively polar, non-volatile oils useful in the present invention are preferably selected from silicone oils; hydrocarbon oils; fatty alcohols; fatty acids; esters of mono and dibasic carboxylic acids with mono and polyhydric alcohols; polyoxyethylenes; polyoxypropylenes; mixtures of polyoxyethylene and polyoxypropylene ethers of fatty alcohols; and mixtures thereof. The relatively polar, non-volatile co-carriers useful in the present invention may be either saturated or unsaturated, have an aliphatic character and be straight or branched chained or contain alicyclic or aromatic rings. More preferably, the relatively polar, non-volatile liquid co-carrier is selected from fatty alcohols having from about 12-26 carbon atoms; fatty acids having from about 12-26 carbon atoms; esters of monobasic carboxylic acids and alcohols having from about 14-30 carbon atoms; esters of dibasic carboxylic acids and alcohols having from about 10-30 carbon atoms; esters of polyhydric alcohols and carboxylic acids having from about 5-26 carbon atoms;

ethoxylated, propoxylated, and mixtures of ethoxylated and propoxylated ethers of fatty alcohols with from about 12-26 carbon atoms and a degree of ethoxylation and propoxylation of below about 50; and mixtures thereof. More preferred are propoxylated ethers of C14 -C18 fatty alcohols having a degree of propoxylation below about 50, esters of C2 -C8 alcohols and C12-C26 carboxylic acids (e.g. ethyl myristate, isopropyl palmitate), esters of C12-C26 alcohols and benzoic acid (e.g. Finsolv TN supplied by Finetex), diesters of C2-C8 alcohols and adipic, sebacic, and phthalic acids (e.g., diisopropyl sebacate, diisopropyl adipate, di-n-butyl phthalate), polyhydric alcohol esters of C6 -C26 carboxylic acids (e.g., propylene glycol dicaprate/dicaprylate, propylene glycol isostearate); and mixtures thereof. Even more preferred are branched-chain aliphatic fatty alcohols having from about 12-26 carbon atoms. Even more preferred is isocetyl alcohol, octyldecanol, octyldodecanol and undecylpentadecanol; and most preferred is octyldodecanol. Such preferred aliphatic fatty alcohols are particularly useful in combination with the volatile liquid silicone oils discussed herein to adjust the average solubility of the carrier.

3. Non-polar, Non-volatile oils

In addition to the liquids discussed above, the carrier for the cross-linked siloxane elastomer may optionally include non-volatile, non-polar oils. Typical non-volatile, non-polar emollients are disclosed, for example, in Cosmetics, Science, and Technology, Vol. 1, 27-104 edited by Balsam and Sagarin, 1972; U.S. Patents 4,202,879 issued to Shelton on May 13, 1980; and 4,816,261 issued to Luebbe et al. on Mar. 28, 1989. Both of which are herein incorporated by reference. The non-volatile oils useful in the present invention are essentially non-volatile polysiloxanes, paraffinic hydrocarbon oils, and mixtures thereof. The polysiloxanes useful in the present invention selected from polyalkylsiloxanes, polyarylsiloxanes, polyalkylarylsiloxanes, poly-ethersiloxane copolymers, and mixtures thereof. Examples of these include polydimethyl siloxanes having viscosities of from about 1 to about 100,000 centistokes at 25° C. Among the preferred non-volatile silicone emollients useful in the present compositions are the polydimethyl siloxanes having viscosities from about 2 to about 400 centistokes at 25° C. Such polyalkylsiloxanes include the Viscasil series (sold by General Electric Company) and the Dow Corning 200 series (sold by Dow Corning Corp.). Polyalkylarylsiloxanes include polymethylphenyl siloxanes having viscosities of from about 15 to about 65 centistokes at 25° C. These are available, for example, as SF 1075 methyl-phenyl fluid (sold by General Electric Company) and 556 Cosmetic Grade Fluid (sold by Dow Corning Corp.). Useful polyethersiloxane copolymers include, for example, a polyoxyalkylene ether

copolymer having a viscosity of about 1200 to 1500 centistokes at 25° C. Such a fluid is available as SF1066 organosilicone surfactant (sold by General Electric Company). Polysiloxane ethylene glycol ether copolymers are preferred copolymers for use in the present compositions.

Non-volatile paraffinic hydrocarbon oils useful in the present invention include mineral oils and certain branched-chain hydrocarbons. Examples of these fluids are disclosed in U.S. Patent 5,019,375 issued to Tanner et al. on May 28, 1991, herein incorporated by reference in its entirety. Preferred mineral oils have the following properties:

(1) viscosity from about 5 centistokes to about 70 centistokes at 40° C.;

(2) density between about 0.82 and 0.89 g/cm3 at 25° C.;

(3) flash point between about 138° C. and about 216° C.; and

(4) carbon chain length between about 14 and about 40 carbon atoms.

Preferred branched chain hydrocarbon oils have the following properties:

(1) density between about 0.79 and about 0.89 g/cm3 at 20° C.

(2) boiling point greater than about 250° C.; and

(3) flash point between about 110° C. and about 200° C.

Particularly preferred branched-chain hydrocarbons include Permethyl 103 A, which contains an average of about 24 carbon atoms; Permethyl 104A, which contains an average of about 68 carbon atoms; Permethyl 102A, which contains an average of about 20 carbon atoms; all of which may be purchased from Permethyl Corporation; and Ethylflo 364 which contains a mixture of 30 carbon atoms and 40 carbon atoms and may be purchased from Ethyl Corp.

Additional carriers useful herein include solvents described in US Patent 5,750,096 to Gerald J. Guskey et al., issued May 12, 1998, herein incorporated by reference in its entirety.

Structuring Agents

The compositions of the present invention, in some embodiments, may further include a structuring agent as part of the delivery system. Structuring agents are particularly preferred when the composition is in the form of an emulsion, and are particularly preferred in the oil-in-water emulsion embodiments of the present invention. Without being limited by theory, it is believed that the structuring agent assists in providing rheological characteristics to the composition which contribute to the stability of the composition. For example, the structuring agent tends to assist in the formation of the liquid crystalline gel network structures. The structuring agent may also function as an emulsifier or surfactant. Compositions of this invention may contain from about 0.1% to about 20%, more preferably from about 0.1% to about 10%, still more preferably from about 0.5% to about 9%, of one or more structuring agents.

Preferred structuring agents for use herein are those having an HLB of from about 1 to about 8 and having a melting point of at least about 45°C. Suitable structuring agents are those selected from saturated C_{14} to C_{30} fatty alcohols, saturated C_{16} to C_{30} fatty alcohols containing from about 1 to about 5 moles of ethylene oxide, saturated C_{16} to C_{30} diols, saturated C_{16} to C_{30} monoglycerol ethers, saturated C_{16} to C_{30} hydroxy fatty acids, C_{14} to C_{30} hydroxylated and nonhydroxylated saturated fatty acids, C_{14} to C_{30} saturated ethoxylated fatty acids, amines and alcohols containing from about 1 to about 5 moles of ethylene oxide diols, C_{14} to C_{30} saturated. glyceryl mono esters with a monoglyceride content of at least 40%, C_{14} to C_{30} saturated polyglycerol esters having from about 1 to about 3 alkyl group and from about 2 to about 3 saturated glycerol units, C_{14} to C_{30} glyceryl mono ethers, C_{14} to C_{30} sorbitan mono/diesters, C_{14} to C_{30} saturated ethoxylated sorbitan mono/diesters with about 1 to about 5 moles of ethylene oxide, C_{14} to C_{30} saturated methyl glucoside esters, C_{14} to C_{30} saturated sucrose mono/diesters, C_{14} to C_{30} saturated ethoxylated methyl glucoside esters with about 1 to about 5 moles of ethylene oxide, C_{14} to C_{30} saturated polyglucosides having an average of between 1 to 2 glucose units and mixtures thereof, having a melting point of at least about 45°C.

Examples of preferred structuring agents for use in compositions of the present invention include stearic acid, palmitic acid, stearyl alcohol, cetyl alcohol, behenyl alcohol, stearic acid, palmitic acid, the polyethylene glycol ether of stearyl alcohol having an average of about 1 to about 5 ethylene oxide units, the polyethylene glycol ether of cetyl alcohol having an average of about 1 to about 5 ethylene oxide units, and mixtures thereof. More preferred are stearyl alcohol, cetyl alcohol, behenyl alcohol, the polyethylene glycol ether of stearyl alcohol having an average of about 2 ethylene oxide units (steareth-2), the polyethylene glycol ether of cetyl alcohol having an average of about 2 ethylene oxide units, and mixtures thereof. Even more preferred structuring agents are selected from stearic acid, palmitic acid, stearyl alcohol, cetyl alcohol, behenyl alcohol, steareth-2, and mixtures thereof.

Thickening Agents

The compositions of the present invention, in some embodiments, may further include one or more thickening agents. When present, the composition preferably includes from about 0.1% to about 5%, more preferably from about 0.1% to about 4%, and still more preferably from about 0.25% to about 3%, by weight of the composition of the thickening agent.

Nonlimiting classes of thickening agents include those selected from the following:

a) Carboxylic Acid Polymers

These polymers are crosslinked compounds containing one or more monomers derived from acrylic acid, substituted acrylic acids, and salts and esters of these acrylic acids and the substituted acrylic acids, wherein the crosslinking agent contains two or more carbon-carbon double bonds and is derived from a polyhydric alcohol. Polymers useful in the present invention are more fully described in U. S. Patent No. 5,087,445, to Haffey et al, issued February 11, 1992; U. S. Patent No. 4,509,949, to Huang et al, issued April 5, 1985; U. S. Patent No. 2,798,053, to Brown, issued July 2, 1957; and in *CTFA International Cosmetic Ingredient Dictionary*, Fourth Edition, 1991, pp. 12 and 80.

Examples of commercially available carboxylic acid polymers useful herein include the carbomers, which are homopolymers of acrylic acid crosslinked with allyl ethers of sucrose or pentaerytritol. The carbomers are available as the Carbopol® 900 series from B.F. Goodrich (e.g., Carbopol® 954). In addition, other suitable carboxylic acid polymeric agents include copolymers of C_{10-30} alkyl acrylates with one or more monomers of acrylic acid, methacrylic acid, or one of their short chain (i.e., C_{1-4} alcohol) esters, wherein the crosslinking agent is an allyl ether of sucrose or pentaerytritol. These copolymers are known as acrylates/C_{10-30} alkyl acrylate crosspolymers and are commercially available as Carbopol® 1342, Carbopol® 1382, PEMULEN TR-1, and PEMULEN TR-2, from B.F. Goodrich. In other words, examples of carboxylic acid polymer thickeners useful herein are those selected from carbomers, acrylates/C_{10}-C_{30} alkyl acrylate crosspolymers, and mixtures thereof.

b) Crosslinked Polyacrylate Polymers

The compositions of the present invention can optionally contain crosslinked polyacrylate polymers useful as thickeners or gelling agents including both cationic and nonionic polymers, with the cationics being generally preferred. Examples of useful crosslinked nonionic polyacrylate polymers and crosslinked cationic polyacrylate polymers are those described in U. S. Patent No. 5,100,660, to Hawe et al, issued March 31, 1992; U. S. Patent No. 4,849,484, to Heard, issued July 18, 1989; U. S. Patent No. 4,835,206, to Farrar et al, issued May 30, 1989; U.S. Patent No. 4,628,078 to Glover et al issued December 9, 1986; U.S. Patent No. 4,599,379 to Flesher et al issued July 8, 1986; and EP 228,868, to Farrar et al, published July 15, 1987.

c) Polyacrylamide Polymers

The compositions of the present invention can optionally contain polyacrylamide polymers, especially nonionic polyacrylamide polymers including substituted branched or

unbranched polymers. More preferred among these polyacrylamide polymers is the nonionic polymer given the CTFA designation polyacrylamide and isoparaffin and laureth-7, available under the Tradename Sepigel 305 from Seppic Corporation (Fairfield, NJ).

Other polyacrylamide polymers useful herein include multi-block copolymers of acrylamides and substituted acrylamides with acrylic acids and substituted acrylic acids. Commercially available examples of these multi-block copolymers include HYPAN SR150H, SS500V, SS500W, SSSA100H, from Lipo Chemicals, Inc., (Patterson, NJ).

d) Polysaccharides

A wide variety of polysaccharides are useful herein. "Polysaccharides" refer to gelling agents which contain a backbone of repeating sugar (i.e., carbohydrate) units. Nonlimiting examples of polysaccharide gelling agents include those selected from cellulose, carboxymethyl hydroxyethylcellulose, cellulose acetate propionate carboxylate, hydroxyethylcellulose, hydroxyethyl ethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, methyl hydroxyethylcellulose, microcrystalline cellulose, sodium cellulose sulfate, and mixtures thereof. Also useful herein are the alkyl substituted celluloses. In these polymers, the hydroxy groups of the cellulose polymer is hydroxyalkylated (preferably hydroxyethylated or hydroxypropylated) to form a hydroxyalkylated cellulose which is then further modified with a C_{10}-C_{30} straight chain or branched chain alkyl group through an ether linkage. Typically these polymers are ethers of C_{10}-C_{30} straight or branched chain alcohols with hydroxyalkylcelluloses. Examples of alkyl groups useful herein include those selected from stearyl, isostearyl, lauryl, myristyl, cetyl, isocetyl, cocoyl (i.e. alkyl groups derived from the alcohols of coconut oil), palmityl, oleyl, linoleyl, linolenyl, ricinoleyl, behenyl, and mixtures thereof. Preferred among the alkyl hydroxyalkyl cellulose ethers is the material given the CTFA designation cetyl hydroxyethylcellulose, which is the ether of cetyl alcohol and hydroxyethylcellulose. This material is sold under the tradename Natrosol® CS Plus from Aqualon Corporation (Wilmington, DE).

Other useful polysaccharides include scleroglucans which are a linear chain of (1-3) linked glucose units with a (1-6) linked glucose every three units, a commercially available example of which is Clearogel™ CS11 from Michel Mercier Products Inc. (Mountainside, NJ).

e) Gums

Other thickening and gelling agents useful herein include materials which are primarily derived from natural sources. Nonlimiting examples of these gelling agent gums include acacia, agar, algin, alginic acid, ammonium alginate, amylopectin, calcium alginate, calcium carrageenan, carnitine, carrageenan, dextrin, gelatin, gellan gum, guar gum, guar

hydroxypropyltrimonium chloride, hectorite, hyaluroinic acid, hydrated silica, hydroxypropyl chitosan, hydroxypropyl guar, karaya gum, kelp, locust bean gum, natto gum, potassium alginate, potassium carrageenan, propylene glycol alginate, sclerotium gum, sodium carboxymethyl dextran, sodium carrageenan, tragacanth gum, xanthan gum, and mixtures thereof.

Preferred compositions of the present invention include a thickening agent selected from carboxylic acid polymers, crosslinked polyacrylate polymers, polyacrylamide polymers, and mixtures thereof, more preferably selected from carboxylic acid polymers, polyacrylamide polymers, and mixtures thereof.

Water

The topical compositions of the present invention may, in some embodiments, further include water at from about 0.1% to about 95%, preferably from about 0.5% to about 90%, more preferably from about 0.1% to about 70%, by weight of the composition.

Suitable Forms

The delivery system herein includes the silicone elastomer, the carrier for the elastomer, and the tacky solvent. The delivery system can be provided in a wide variety of forms. For example, emulsion delivery systems, including, but not limited to, oil-in-water, water-in-oil, water-in-silicone, water-in-oil-in-water, and oil-in-water-in-silicone emulsions, are useful herein. Other suitable forms include anhydrous mixtures such as mixtures of glycerin and silicone. Preferred delivery systems contain an emulsion such as oil-in-water, water-in-oil emulsions, and water-in-silicone emulsions. As will be understood by the skilled artisan, a given component will distribute primarily into either the water or oil/silicone phase, depending on the water solubility/dispersibility of the component in the composition.

When the composition is in emulsion form, the composition will preferably further contain from about 0.01% to about 10%, more preferably from about 0.1% to about 5%, of an emulsifier, based on the weight of the delivery system. Emulsifiers may be nonionic, anionic or cationic. Suitable emulsifiers are disclosed in, for example, U.S. Patent 3,755,560, issued August 28, 1973, Dickert et al.; U.S. Patent 4,421,769, issued December 20, 1983, Dixon et al.; and McCutcheon's Detergents and Emulsifiers, North American Edition, pages 317-324 (1986). Examples of suitable emulsifiers can also be found in U.S. Patent 5,085,856 to Dunphy et al. and U.S. patent 5,688,831 to El-Nokaly et al., both of which are incorporated herein by reference.

The emulsion may also contain an anti-foaming agent to minimize foaming upon application to the keratinous tissue. Anti-foaming agents include high molecular weight silicones and other materials well known in the art for such use.

Suitable emulsions may have a wide range of viscosities, depending on the desired product form.

Preferred water-in-silicone and oil-in-water emulsions are described in greater detail below.

a) Water-in-silicone emulsion

Water-in-silicone emulsions are well known in the art and contain a continuous silicone phase and a dispersed aqueous phase.

1) Continuous silicone phase

Preferred water-in-silicone emulsions of the present invention contain from about 1% to about 80%, preferably from about 5% to about 50%, more preferably from about 5% to about 40%, by weight of a continuous silicone phase. The continuous silicone phase exists as an external phase that contains or surrounds the discontinuous aqueous phase described hereinafter.

The continuous silicone phase contains a polyorganosiloxane oil. The continuous silicone phase of these preferred emulsions contain between about 50% and about 99.9% by weight of organopolysiloxane oil and less than about 50% by weight of a non-silicone oil. In an especially preferred embodiment, the continuous silicone phase contains at least about 50%, preferably from about 60% to about 99.9%, more preferably from about 70% to about 99.9%, and even more preferably from about 80% to about 99.9%, polyorganosiloxane oil by weight of the continuous silicone phase, and up to about 50% non-silicone oils, preferably less about 40%, more preferably less than about 30%, even more preferably less than about 10%, and even more preferably less than about 2%, by weight of the continuous silicone phase. These preferred emulsion systems provide more oxidative stability to the composition over extended periods of time than comparable water-in-oil emulsions containing lower concentrations of the polyorganosiloxane oil. Water-in-silicone emulsions of this type are described in PCT Application WO 97/21423, published June 19, 1997.

The organopolysiloxane oil for use in the composition may be volatile, non-volatile, or a mixture of volatile and non-volatile silicones. The term "nonvolatile" as used in this context refers to those silicones that are liquid under ambient conditions and have a flash point (under one atmospheric of pressure) of or greater than about 100°C. The term "volatile" as used in this context refers to all other silicone oils. Suitable organopolysiloxanes can be selected from a wide variety of silicones spanning a broad range of volatilities and viscosities. Examples of suitable organopolysiloxane oils include polyalkylsiloxanes, cyclic polyalkylsiloxanes, and polyalkylarylsiloxanes.

Polyalkylsiloxanes useful in the composition herein include polyalkylsiloxanes with viscosities of from about 0.5 to about 1,000,000 centistokes at 25°C. Such polyalkylsiloxanes can be represented by the general chemical formula $R_3SiO[R_2SiO]_xSiR_3$ wherein R is an alkyl group having from one to about 30 carbon atoms (preferably R is methyl or ethyl, more preferably methyl; also mixed alkyl groups can be used in the same molecule), and x is an integer from 0 to about 10,000, chosen to achieve the desired molecular weight which can range to over about 10,000,000. Commercially available polyalkylsiloxanes include the polydimethylsiloxanes, which are also known as dimethicones, examples of which include the Vicasil® series sold by General Electric Company and the Dow Corning® 200 series sold by Dow Corning Corporation. Specific examples of suitable polydimethylsiloxanes include Dow Corning® 200 fluid having a viscosity of 0.65 centistokes and a boiling point of 100°C, Dow Corning® 225 fluid having a viscosity of 10 centistokes and a boiling point greater than 200°C, and Dow Corning® 200 fluids having viscosities of 50, 350, and 12,500 centistokes, respectively, and boiling points greater than 200°C. Suitable dimethicones include those represented by the chemical formula $(CH_3)_3SiO[(CH_3)_2SiO]_x[CH_3RSiO]_ySi(CH_3)_3$ wherein R is straight or branched chain alkyl having from two to about 30 carbon atoms and x and y are each integers of 1 or greater selected to achieve the desired molecular weight which can range to over about 10,000,000. Examples of these alkyl-substituted dimethicones include cetyl dimethicone and lauryl dimethicone.

Cyclic polyalkylsiloxanes suitable for use in the composition include those represented by the chemical formula $[SiR_2\text{-}O]_n$ wherein R is an alkyl group (preferably R is methyl or ethyl, more preferably methyl) and n is an integer from about 3 to about 8, more preferably n is an integer from about 3 to about 7, and still more preferably n is an integer from about 4 to about 6. When R is methyl, these materials are typically referred to as cyclomethicones. Commercially available cyclomethicones include Dow Corning® 244 fluid having a viscosity of 2.5 centistokes, and a boiling point of 172°C, which primarily contains the cyclomethicone tetramer (i.e. n=4), Dow Corning® 344 fluid having a viscosity of 2.5 centistokes and a boiling point of 178°C, which primarily contains the cyclomethicone pentamer (i.e. n=5), Dow Corning® 245 fluid having a viscosity of 4.2 centistokes and a boiling point of 205°C, which primarily contains a mixture of the cyclomethicone tetramer and pentamer (i.e. n=4 and 5), and Dow Corning® 345

fluid having a viscosity of 4.5 centistokes and a boiling point of 217°, which primarily contains a mixture of the cyclomethicone tetramer, pentamer, and hexamer (i.e. n=4, 5, and 6).

Also useful are materials such as trimethylsiloxysilicate, which is a polymeric material corresponding to the general chemical formula $[(CH_2)_3SiO_{1/2}]_x[SiO_2]y$, wherein x is an integer from about 1 to about 500 and y is an integer from about 1 to about 500. A commercially available trimethylsiloxysilicate is sold as a mixture with dimethicone as Dow Corning® 593 fluid.

Dimethiconols are also suitable for use in the composition. These compounds can be represented by the chemical formulas $R_3SiO[R_2SiO]_xSiR_2OH$ and $HOR_2SiO[R_2SiO]_xSiR_2OH$ wherein R is an alkyl group (preferably R is methyl or ethyl, more preferably methyl) and x is an integer from 0 to about 500, chosen to achieve the desired molecular weight. Commercially available dimethiconols are typically sold as mixtures with dimethicone or cyclomethicone (e.g. Dow Corning® 1401, 1402, and 1403 fluids).

Polyalkylaryl siloxanes are also suitable for use in the composition. Polymethylphenyl siloxanes having viscosities from about 15 to about 65 centistokes at 25°C are especially useful.

Preferred for use herein are organopolysiloxanes selected from polyalkylsiloxanes, alkyl substituted dimethicones, cyclomethicones, trimethylsiloxysilicates, dimethiconols, polyalkylaryl siloxanes, and mixtures thereof. More preferred for use herein are polyalkylsiloxanes and cyclomethicones. Preferred among the polyalkylsiloxanes are dimethicones.

As stated above, the continuous silicone phase may contain one or more non-silicone oils. Concentrations of non-silicone oils in the continuous silicone phase are preferably minimized or avoided altogether so as to further enhance oxidative stability of the selected retinoid in the compositions. Suitable non-silicone oils have a melting point of about 25°C or less under about one atmosphere of pressure. Examples of non-silicone oils suitable for use in the continuous silicone phase are those well known in the chemical arts in topical personal care products in the form of water-in-oil emulsions, e.g., mineral oil, vegetable oils, synthetic oils, semisynthetic oils, etc.

(2) Dispersed aqueous phase

The topical compositions of the present invention contain from about 20% to about 90%, more preferably from about 30% to about 85%, and still more preferably from about 40% to about 80% of a dispersed aqueous phase. In emulsion technology, the term "dispersed phase" is a term well-known to one skilled in the art which means that the phase exists as small particles or

droplets that are suspended in and surrounded by a continuous phase. The dispersed phase is also known as the internal or discontinuous phase. The dispersed aqueous phase is a dispersion of small aqueous particles or droplets suspended in and surrounded by the continuous silicone phase described hereinbefore.

The aqueous phase can be water, or a combination of water and one or more water soluble or dispersible ingredients. Nonlimiting examples of such ingredients include thickeners, acids, bases, salts, chelants, gums, water-soluble or dispersible alcohols and polyols, buffers, preservatives, sunscreening agents, colorings, and the like.

(3) Emulsifier for dispersing the aqueous phase

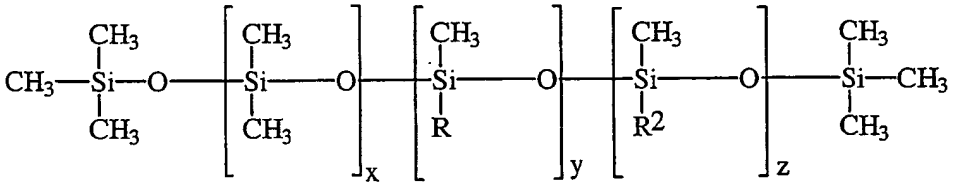
The water-in-silicone emulsions of the present invention can contain an emulsifier other than or in addition to an emulsifying elastomer. In some embodiments, the composition may contain from about 0.1% to about 10% emulsifier, more preferably from about 0.5% to about 7.5%, still more preferably from about 1% to about 5%, emulsifier by weight of the composition. The emulsifier helps disperse and suspend the aqueous phase within the continuous silicone phase.

A wide variety of emulsifying agents can be employed herein to form the preferred water-in-silicone emulsion. Known or conventional emulsifying agents can be used in the composition, provided that the selected emulsifying agent is chemically and physically compatible with components of the composition of the present invention, and provides the desired dispersion characteristics. Suitable emulsifiers include silicone emulsifiers, non-silicon-containing emulsifiers, and mixtures thereof, known by those skilled in the art for use in topical personal care products. Preferably these emulsifiers have an HLB value of or less than about 14, more preferably from about 2 to about 14, and still more preferably from about 4 to about 14. Emulsifiers having an HLB value outside of these ranges can be used in combination with other emulsifiers to achieve an effective weighted average HLB for the combination that falls within these ranges.

Silicone emulsifiers are preferred. A wide variety of silicone emulsifiers are useful herein. These silicone emulsifiers are typically organically modified organopolysiloxanes, also known to those skilled in the art as silicone surfactants. Useful silicone emulsifiers include dimethicone copolyols. These materials are polydimethyl siloxanes which have been modified to include polyether side chains such as polyethylene oxide chains, polypropylene oxide chains, mixtures of these chains, and polyether chains containing moieties derived from both ethylene oxide and propylene oxide. Other examples include alkyl-modified dimethicone copolyols, i.e., compounds

which contain C2-C30 pendant side chains. Still other useful dimethicone copolyols include materials having various cationic, anionic, amphoteric, and zwitterionic pendant moieties.

The dimethicone copolyol emulsifiers useful herein can be described by the following general structure:



wherein R is C1-C30 straight, branched, or cyclic alkyl and R^2 is selected from:

$$-(CH_2)_n-O-(CH_2CHR^3O)_m-H,$$

and

$$-(CH_2)_n-O-(CH_2CHR^3O)_m-(CH_2CHR^4O)_o-H,$$

wherein n is an integer from 3 to about 10; R^3 and R^4 are selected from H and C1-C6 straight or branched chain alkyl such that R^3 and R^4 are not simultaneously the same; and m, o, x, and y are selected such that the molecule has an overall molecular weight from about 200 to about 10,000,000, with m, o, x, and y being independently selected from integers of zero or greater such that m and o are not both simultaneously zero, and z being independently selected from integers of 1 or greater. It is recognized that positional isomers of these copolyols can be achieved. The chemical representations depicted above for the R^2 moieties containing the R^3 and R^4 groups are not meant to be limiting but are shown as such for convenience.

Also useful herein, although not strictly classified as dimethicone copolyols, are silicone surfactants as depicted in the structures in the previous paragraph wherein R^2 is:

$$-(CH_2)_n-O-R^5,$$

wherein R^5 is a cationic, anionic, amphoteric, or zwitterionic moiety.

Nonlimiting examples of dimethicone copolyols and other silicone surfactants useful as emulsifiers herein include polydimethylsiloxane polyether copolymers with pendant polyethylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant polypropylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant mixed polyethylene oxide and polypropylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant mixed poly(ethylene)(propylene)oxide sidechains, polydimethylsiloxane polyether copolymers with pendant organobetaine sidechains, polydimethylsiloxane polyether copolymers with pendant

carboxylate sidechains, polydimethylsiloxane polyether copolymers with pendant quaternary ammonium sidechains; and also further modifications of the preceding copolymers containing pendant C2-C30 straight, branched, or cyclic alkyl moieties. Examples of commercially available dimethicone copolyols useful herein sold by Dow Corning Corporation are Dow Corning® 190, 193, Q2-5220, 2501 Wax, 2-5324 fluid, and 3225C (this later material being sold as a mixture with cyclomethicone). Cetyl dimethicone copolyol is commercially available as a mixture with polyglyceryl-4 isostearate (and) hexyl laurate and is sold under the tradename ABIL® WE-09 (available from Goldschmidt). Cetyl dimethicone copolyol is also commercially available as a mixture with hexyl laurate (and) polyglyceryl-3 oleate (and) cetyl dimethicone and is sold under the tradename ABIL® WS-08 (also available from Goldschmidt). Other nonlimiting examples of dimethicone copolyols also include lauryl dimethicone copolyol, dimethicone copolyol acetate, dimethicone copolyol adipate, dimethicone copolyolamine, dimethicone copolyol behenate, dimethicone copolyol butyl ether, dimethicone copolyol hydroxy stearate, dimethicone copolyol isostearate, dimethicone copolyol laurate, dimethicone copolyol methyl ether, dimethicone copolyol phosphate, and dimethicone copolyol stearate. See International Cosmetic Ingredient Dictionary, Fifth Edition, 1993.

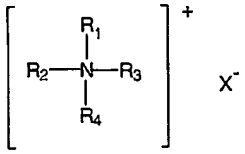
Dimethicone copolyol emulsifiers useful herein are described, for example, in U.S. Patent No. 4,960,764, to Figueroa, Jr. et al., issued October 2, 1990; European Patent No. EP 330,369, to SanoGueira, published August 30, 1989; G.H. Dahms, et al., "New Formulation Possibilities Offered by Silicone Copolyols," Cosmetics & Toiletries, vol. 110, pp. 91-100, March 1995; M.E. Carlotti et al., "Optimization of W/O-S Emulsions And Study Of The Quantitative Relationships Between Ester Structure And Emulsion Properties," J. Dispersion Science And Technology, 13(3), 315-336 (1992); P. Hameyer, "Comparative Technological Investigations of Organic and Organosilicone Emulsifiers in Cosmetic Water-in-Oil Emulsion Preparations," HAPPI 28(4), pp. 88-128 (1991); J. Smid-Korbar et al., "Efficiency and usability of silicone surfactants in emulsions," Provisional Communication, International Journal of Cosmetic Science, **12**, 135-139 (1990); and D.G. Krzysik et al., "A New Silicone Emulsifier For Water-in-Oil Systems," Drug and Cosmetic Industry, vol. 146(4) pp. 28-81 (April 1990).

Among the non-silicone-containing emulsifiers useful herein are various non-ionic and anionic emulsifying agents such as sugar esters and polyesters, alkoxylated sugar esters and polyesters, C1-C30 fatty acid esters of C1-C30 fatty alcohols, alkoxylated derivatives of C1-C30 fatty acid esters of C1-C30 fatty alcohols, alkoxylated ethers of C1-C30 fatty alcohols,

polyglyceryl esters of C1-C30 fatty acids, C1-C30 esters of polyols, C1-C30 ethers of polyols, alkyl phosphates, polyoxyalkylene fatty ether phosphates, fatty acid amides, acyl lactylates, soaps, and mixtures thereof. Other suitable emulsifiers are described, for example, in McCutcheon's, Detergents and Emulsifiers, North American Edition (1986), published by Allured Publishing Corporation; U.S. Patent No. 5,011,681 to Ciotti et al., issued April 30, 1991; U.S. Patent No. 4,421,769 to Dixon et al., issued December 20, 1983; and U.S. Patent No. 3,755,560 to Dickert et al., issued August 28, 1973.

Other suitable surfactants useful herein include a wide variety of cationic, anionic, zwitterionic, and amphoteric surfactants such as are known in the art and discussed more fully below. See, e.g., McCutcheon's, Detergents and Emulsifiers, North American Edition (1986), published by Allured Publishing Corporation; U.S. Patent No. 5,011,681 to Ciotti et al., issued April 30, 1991; U.S. Patent No. 4,421,769 to Dixon et al., issued December 20, 1983; and U.S. Patent No. 3,755,560 to Dickert et al., issued August 28, 1973; these four references are incorporated herein by reference in their entirety. The hydrophilic surfactants useful herein can contain a single surfactant, or any combination of suitable surfactants. The exact surfactant (or surfactants) chosen will depend upon the pH of the composition and the other components present.

Cationic surfactants useful herein include dialkyl quaternary ammonium compounds, examples of which are described in U.S. Patent 5,151,209; U.S. Patent 5,151,210; U.S. Patent 5,120,532; U.S. Patent 4,387,090; U.S. Patent 3,155,591; U.S. Patent 3,929,678; U.S. Patent 3,959,461; McCutcheon's, Detergents & Emulsifiers, (North American edition 1979) M.C. Publishing Co.; and Schwartz, et al., Surface Active Agents, Their Chemistry and Technology, New York: Interscience Publishers, 1949; which descriptions are incorporated herein by reference. The cationic surfactants useful herein also include cationic ammonium salts such as those having the formula:



wherein R_1, is an alkyl group having from about 12 to about 30 carbon atoms, or an aromatic, aryl or alkaryl group having from about 12 to about 30 carbon atoms; R_2, R_3, and R_4 are independently selected from hydrogen, an alkyl group having from about 1 to about 22 carbon atoms, or aromatic, aryl or alkaryl groups having from about 12 to about 22 carbon atoms; and X

is any compatible anion, preferably selected from chloride, bromide, iodide, acetate, phosphate, nitrate, sulfate, methyl sulfate, ethyl sulfate, tosylate, lactate, citrate, glycolate, and mixtures thereof. Additionally, the alkyl groups of R_1, R_2, R_3, and R_4 can also contain ester and/or ether linkages, or hydroxy or amino group substituents (e.g., the alkyl groups can contain polyethylene glycol and polypropylene glycol moieties).

More preferably, R_1 is an alkyl group having from about 12 to about 22 carbon atoms; R_2 is selected from H or an alkyl group having from about 1 to about 22 carbon atoms; R_3 and R_4 are independently selected from H or an alkyl group having from about 1 to about 3 carbon atoms; and X is as described previously.

Still more preferably, R_1 is an alkyl group having from about 12 to about 22 carbon atoms; R_2, R_3, and R_4 are selected from H or an alkyl group having from about 1 to about 3 carbon atoms; and X is as described previously.

Alternatively, other useful cationic emulsifiers include amino-amides, wherein in the above structure R_1 is alternatively $R_5CONH\text{-}(CH_2)_n$, wherein R_5 is an alkyl group having from about 12 to about 22 carbon atoms, and n is an integer from about 2 to about 6, more preferably from about 2 to about 4, and still more preferably from about 2 to about 3. Nonlimiting examples of these cationic emulsifiers include stearamidopropyl PG-dimonium chloride phosphate, behenamidopropyl PG dimonium chloride, stearamidopropyl ethyldimonium ethosulfate, stearamidopropyl dimethyl (myristyl acetate) ammonium chloride, stearamidopropyl dimethyl cetearyl ammonium tosylate, stearamidopropyl dimethyl ammonium chloride, stearamidopropyl dimethyl ammonium lactate, and mixtures thereof. Especially preferred is behenamidopropyl PG dimonium chloride.

Nonlimiting examples of quaternary ammonium salt cationic surfactants include those selected from cetyl ammonium chloride, cetyl ammonium bromide, lauryl ammonium chloride, lauryl ammonium bromide, stearyl ammonium chloride, stearyl ammonium bromide, cetyl dimethyl ammonium chloride, cetyl dimethyl ammonium bromide, lauryl dimethyl ammonium chloride, lauryl dimethyl ammonium bromide, stearyl dimethyl ammonium chloride, stearyl dimethyl ammonium bromide, cetyl trimethyl ammonium chloride, cetyl trimethyl ammonium bromide, lauryl trimethyl ammonium chloride, lauryl trimethyl ammonium bromide, stearyl trimethyl ammonium chloride, stearyl trimethyl ammonium bromide, lauryl dimethyl ammonium chloride, stearyl dimethyl cetyl ditallow dimethyl ammonium chloride, dicetyl ammonium chloride, dicetyl ammonium bromide, dilauryl ammonium chloride, dilauryl ammonium bromide,

distearyl ammonium chloride, distearyl ammonium bromide, dicetyl methyl ammonium chloride, dicetyl methyl ammonium bromide, dilauryl methyl ammonium chloride, dilauryl methyl ammonium bromide, distearyl methyl ammonium chloride, distearyl methyl ammonium bromide, and mixtures thereof. Additional quaternary ammonium salts include those wherein the C_{12} to C_{30} alkyl carbon chain is derived from a tallow fatty acid or from a coconut fatty acid. The term "tallow" refers to an alkyl group derived from tallow fatty acids (usually hydrogenated tallow fatty acids), which generally have mixtures of alkyl chains in the C_{16} to C_{18} range. The term "coconut" refers to an alkyl group derived from a coconut fatty acid, which generally have mixtures of alkyl chains in the C_{12} to C_{14} range. Examples of quaternary ammonium salts derived from these tallow and coconut sources include ditallow dimethyl ammonium chloride, ditallow dimethyl ammonium methyl sulfate, di(hydrogenated tallow) dimethyl ammonium chloride, di(hydrogenated tallow) dimethyl ammonium acetate, ditallow dipropyl ammonium phosphate, ditallow dimethyl ammonium nitrate, di(coconutalkyl)dimethyl ammonium chloride, di(coconutalkyl)dimethyl ammonium bromide, tallow ammonium chloride, coconut ammonium chloride, stearamidopropyl PG-dimonium chloride phosphate, stearamidopropyl ethyldimonium ethosulfate, stearamidopropyl dimethyl (myristyl acetate) ammonium chloride, stearamidopropyl dimethyl cetearyl ammonium tosylate, stearamidopropyl dimethyl ammonium chloride, stearamidopropyl dimethyl ammonium lactate, and mixtures thereof. An example of a quaternary ammonium compound having an alkyl group with an ester linkage is ditallowyl oxyethyl dimethyl ammonium chloride.

More preferred cationic surfactants are those selected from behenamidopropyl PG dimonium chloride, dilauryl dimethyl ammonium chloride, distearyl dimethyl ammonium chloride, dimyristyl dimethyl ammonium chloride, dipalmityl dimethyl ammonium chloride, distearyl dimethyl ammonium chloride, stearamidopropyl PG-dimonium chloride phosphate, stearamidopropyl ethyldiammonium ethosulfate, stearamidopropyl dimethyl (myristyl acetate) ammonium chloride, stearamidopropyl dimethyl cetearyl ammonium tosylate, stearamidopropyl dimethyl ammonium chloride, stearamidopropyl dimethyl ammonium lactate, and mixtures thereof.

Still more preferred cationic surfactants are those selected from behenamidopropyl PG dimonium chloride, dilauryl dimethyl ammonium chloride, distearyl dimethyl ammonium chloride, dimyristyl dimethyl ammonium chloride, dipalmityl dimethyl ammonium chloride, and mixtures thereof.

A preferred combination of cationic surfactant and structuring agent is behenamidopropyl PG dimonium chloride and/or behenyl alcohol, wherein the ratio is preferably optimized to maintained to enhance physical and chemical stability, especially when such a combination contains ionic and/or highly polar solvents. This combination is especially useful for delivery of sunscreening agents such as zinc oxide and octyl methoxycinnamate.

A wide variety of anionic surfactants are also useful herein. See, e.g., U.S. Patent No. 3,929,678, to Laughlin et al., issued December 30, 1975, which is incorporated herein by reference in its entirety. Nonlimiting examples of anionic surfactants include the alkoyl isethionates, and the alkyl and alkyl ether sulfates. The alkoyl isethionates typically have the formula $RCO\text{-}OCH_2CH_2SO_3M$ wherein R is alkyl or alkenyl of from about 10 to about 30 carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium and triethanolamine. Nonlimiting examples of these isethionates include those alkoyl isethionates selected from ammonium cocoyl isethionate, sodium cocoyl isethionate, sodium lauroyl isethionate, sodium stearoyl isethionate, and mixtures thereof.

b) Oil-in-Water Emulsions Other preferred topical carriers include oil-in-water emulsions, having a continuous aqueous phase and a hydrophobic, water-insoluble phase ("oil phase") dispersed therein. Examples of suitable oil-in-water emulsion carriers are described in U.S. Pat. No. 5,073,371, to Turner, D.J. et al., issued Dec. 17, 1991, and U.S. Pat. No. 5,073,372, to Turner, D.J. et al., issued Dec. 17, 1991. An especially preferred oil-in-water emulsion, containing a structuring agent, hydrophilic surfactant and water, is described in detail hereinafter.

(1) Structuring Agent

A preferred oil-in-water emulsion contains a structuring agent to assist in the formation of a liquid crystalline gel network structure. Without being limited by theory, it is believed that the structuring agent assists in providing rheological characteristics to the composition which contribute to the stability of the composition. The structuring agent may also function as an emulsifier or surfactant. Preferred compositions of this invention contain from about 0.5% to about 20%, more preferably from about 1% to about 10%, even more preferably from about 1% to about 5%, by weight of the composition, of a structuring agent.

The preferred structuring agents of the present invention include stearic acid, palmitic acid, stearyl alcohol, cetyl alcohol, behenyl alcohol, stearic acid, palmitic acid, the polyethylene glycol ether of stearyl alcohol having an average of about 1 to about 21 ethylene oxide units, the polyethylene glycol ether of cetyl alcohol having an average of about 1 to about 5 ethylene oxide units, and mixtures thereof. More preferred structuring agents of the present invention are

selected from stearyl alcohol, cetyl alcohol, behenyl alcohol, the polyethylene glycol ether of stearyl alcohol having an average of about 2 ethylene oxide units (steareth-2), the polyethylene glycol ether of stearyl alcohol having an average of about 21 ethylene oxide units (steareth-21), the polyethylene glycol ether of cetyl alcohol having an average of about 2 ethylene oxide units, and mixtures thereof. Even more preferred structuring agents are selected from stearic acid, palmitic acid, stearyl alcohol, cetyl alcohol, behenyl alcohol, steareth-2, steareth-21, and mixtures thereof.

(2) Hydrophilic surfactant

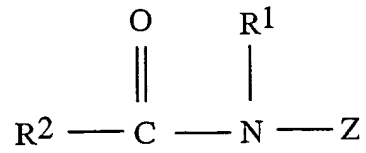
The preferred oil-in-water emulsions contain from about 0.05% to about 10%, preferably from about 1% to about 6%, and more preferably from about 1% to about 4% of at least one hydrophilic surfactant which can disperse the hydrophobic materials in the water phase (percentages by weight of the topical carrier). The surfactant, at a minimum, must be hydrophilic enough to disperse in water.

Preferred hydrophilic surfactants are selected from nonionic surfactants. Among the nonionic surfactants that are useful herein are those that can be broadly defined as condensation products of long chain alcohols, e.g. C8-30 alcohols, with sugar or starch polymers, i.e., glycosides. These compounds can be represented by the formula $(S)_n$-O-R wherein S is a sugar moiety such as glucose, fructose, mannose, and galactose; n is an integer of from about 1 to about 1000, and R is a C8-30 alkyl group. Examples of long chain alcohols from which the alkyl group can be derived include decyl alcohol, cetyl alcohol, stearyl alcohol, lauryl alcohol, myristyl alcohol, oleyl alcohol, and the like. Preferred examples of these surfactants include those wherein S is a glucose moiety, R is a C8-20 alkyl group, and n is an integer of from about 1 to about 9. Commercially available examples of these surfactants include decyl polyglucoside (available as APG 325 CS from Henkel) and lauryl polyglucoside (available as APG 600 CS and 625 CS from Henkel).

Other useful nonionic surfactants include the condensation products of alkylene oxides with fatty acids (i.e. alkylene oxide esters of fatty acids). These materials have the general formula $RCO(X)_nOH$ wherein R is a C10-30 alkyl group, X is $-OCH_2CH_2-$ (i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 200. Other nonionic surfactants are the condensation products of alkylene oxides with 2 moles of fatty acids (i.e. alkylene oxide diesters of fatty acids). These materials have the general formula $RCO(X)_nOOCR$ wherein R is a C10-30 alkyl

group, X is $-OCH_2CH_2-$(i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$(i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 100. Other nonionic surfactants are the condensation products of alkylene oxides with fatty alcohols (i.e. alkylene oxide ethers of fatty alcohols). These materials have the general formula $R(X)_nOR'$ wherein R is a C10-30 alkyl group, X is $-OCH_2CH_2-$(i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 100 and R′ is H or a C10-30 alkyl group. Still other nonionic surfactants are the condensation products of alkylene oxides with both fatty acids and fatty alcohols [i.e. wherein the polyalkylene oxide portion is esterified on one end with a fatty acid and etherified (i.e. connected via an ether linkage) on the other end with a fatty alcohol]. These materials have the general formula $RCO(X)_nOR'$ wherein R and R′ are C10-30 alkyl groups, X is $-OCH_2CH_2$ (i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (derived from propylene glycol or oxide), and n is an integer from about 6 to about 100. Nonlimiting examples of these alkylene oxide derived nonionic surfactants include ceteth-6, ceteth-10, ceteth-12, ceteareth-6, ceteareth-10, ceteareth-12, steareth-6, steareth-10, steareth-12, steareth-21, PEG-6 stearate, PEG-10 stearate, PEG-100 stearate, PEG-12 stearate, PEG-20 glyceryl stearate, PEG-80 glyceryl tallowate, PEG-10 glyceryl stearate, PEG-30 glyceryl cocoate, PEG-80 glyceryl cocoate, PEG-200 glyceryl tallowate, PEG-8 dilaurate, PEG-10 distearate, and mixtures thereof.

Still other useful nonionic surfactants include polyhydroxy fatty acid amide surfactants corresponding to the structural formula:



wherein: R^1 is H, C_1-C_4 alkyl, 2-hydroxyethyl, 2-hydroxy- propyl, preferably C_1-C_4 alkyl, more preferably methyl or ethyl, most preferably methyl; R^2 is C_5-C_{31} alkyl or alkenyl, preferably C_7-C_{19} alkyl or alkenyl, more preferably C_9-C_{17} alkyl or alkenyl, most preferably C_{11}-C_{15} alkyl or alkenyl; and Z is a polhydroxyhydrocarbyl moiety having a linear hydrocarbyl chain with a least 3 hydroxyls directly connected to the chain, or an alkoxylated derivative (preferably

ethoxylated or propoxylated) thereof. Z preferably is a sugar moiety selected from glucose, fructose, maltose, lactose, galactose, mannose, xylose, and mixtures thereof. An especially preferred surfactant corresponding to the above structure is coconut alkyl N-methyl glucoside amide (i.e., wherein the R^2CO- moiety is derived from coconut oil fatty acids). Processes for making compositions containing polyhydroxy fatty acid amides are disclosed, for example, in G.B. Patent Specification 809,060, published February 18, 1959, by Thomas Hedley & Co., Ltd.; U.S. Patent No. 2,965,576, to E. R. Wilson, issued December 20, 1960; U.S. Patent No. 2,703,798, to A. M. Schwartz, issued March 8, 1955; and U.S. Patent No. 1,985,424, to Piggott, issued December 25, 1934; which are incorporated herein by reference in their entirety.

Preferred among the nonionic surfactants are those selected from steareth-21, ceteareth-20, ceteareth-12, sucrose cocoate, steareth-100, PEG-100 stearate, and mixtures thereof.

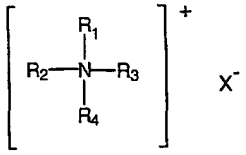
Other nonionic surfactants suitable for use herein include sugar esters and polyesters, alkoxylated sugar esters and polyesters, C1-C30 fatty acid esters of C1-C30 fatty alcohols, alkoxylated derivatives of C1-C30 fatty acid esters of C1-C30 fatty alcohols, alkoxylated ethers of C1-C30 fatty alcohols, polyglyceryl esters of C1-C30 fatty acids, C1-C30 esters of polyols, C1-C30 ethers of polyols, alkyl phosphates, polyoxyalkylene fatty ether phosphates, fatty acid amides, acyl lactylates, and mixtures thereof. Nonlimiting examples of these emulsifiers include: polyethylene glycol 20 sorbitan monolaurate (Polysorbate 20), polyethylene glycol 5 soya sterol, Steareth-20, Ceteareth-20, PPG-2 methyl glucose ether distearate, Ceteth-10, Polysorbate 80, cetyl phosphate, potassium cetyl phosphate, diethanolamine cetyl phosphate, Polysorbate 60, glyceryl stearate, polyoxyethylene 20 sorbitan trioleate (Polysorbate 85), sorbitan monolaurate, polyoxyethylene 4 lauryl ether sodium stearate, polyglyceryl-4 isostearate, hexyl laurate, PPG-2 methyl glucose ether distearate, PEG-100 stearate, and mixtures thereof.

Another group of non-ionic surfactants useful herein are fatty acid ester blends based on a mixture of sorbitan or sorbitol fatty acid ester and sucrose fatty acid ester, the fatty acid in each instance being preferably C_8-C_{24}, more preferably C_{10}-C_{20}. The preferred fatty acid ester emulsifier is a blend of sorbitan or sorbitol C_{16}-C_{20} fatty acid ester with sucrose C_{10}-C_{16} fatty acid ester, especially sorbitan stearate and sucrose cocoate. This is commercially available from ICI under the trade name Arlatone 2121.

Other suitable surfactants useful herein include a wide variety of cationic, anionic, zwitterionic, and amphoteric surfactants such as are known in the art and discussed more fully below. See, e.g., McCutcheon's, Detergents and Emulsifiers, North American Edition (1986),

published by Allured Publishing Corporation; U.S. Patent No. 5,011,681 to Ciotti et al., issued April 30, 1991; U.S. Patent No. 4,421,769 to Dixon et al., issued December 20, 1983; and U.S. Patent No. 3,755,560 to Dickert et al., issued August 28, 1973; these four references are incorporated herein by reference in their entirety. The hydrophilic surfactants useful herein can contain a single surfactant, or any combination of suitable surfactants. The exact surfactant (or surfactants) chosen will depend upon the pH of the composition and the other components present.

Also useful herein are cationic surfactants, especially dialkyl quaternary ammonium compounds, examples of which are described in U.S. Patent 5,151,209; U.S. Patent 5,151,210; U.S. Patent 5,120,532; U.S. Patent 4,387,090; U.S. Patent 3,155,591; U.S. Patent 3,929,678; U.S. Patent 3,959,461; McCutcheon's, Detergents & Emulsifiers, (North American edition 1979) M.C. Publishing Co.; and Schwartz, et al., Surface Active Agents, Their Chemistry and Technology, New York: Interscience Publishers, 1949; which descriptions are incorporated herein by reference. The cationic surfactants useful herein include cationic ammonium salts such as those having the formula:



wherein R_1, is an alkyl group having from about 12 to about 30 carbon atoms, or an aromatic, aryl or alkaryl group having from about 12 to about 30 carbon atoms; R_2, R_3, and R_4 are independently selected from hydrogen, an alkyl group having from about 1 to about 22 carbon atoms, or aromatic, aryl or alkaryl groups having from about 12 to about 22 carbon atoms; and X is any compatible anion, preferably selected from chloride, bromide, iodide, acetate, phosphate, nitrate, sulfate, methyl sulfate, ethyl sulfate, tosylate, lactate, citrate, glycolate, and mixtures thereof. Additionally, the alkyl groups of R_1, R_2, R_3, and R_4 can also contain ester and/or ether linkages, or hydroxy or amino group substituents (e.g., the alkyl groups can contain polyethylene glycol and polypropylene glycol moieties).

More preferably, R_1 is an alkyl group having from about 12 to about 22 carbon atoms; R_2 is selected from H or an alkyl group having from about 1 to about 22 carbon atoms; R_3 and R_4 are independently selected from H or an alkyl group having from about 1 to about 3 carbon atoms; and X is as described previously.

Still more preferably, R_1 is an alkyl group having from about 12 to about 22 carbon atoms; R_2, R_3, and R_4 are selected from H or an alkyl group having from about 1 to about 3 carbon atoms; and X is as described previously.

Alternatively, other useful cationic emulsifiers include amino-amides, wherein in the above structure R_1 is alternatively $R_5CONH\text{-}(CH_2)_n$, wherein R_5 is an alkyl group having from about 12 to about 22 carbon atoms, and n is an integer from about 2 to about 6, more preferably from about 2 to about 4, and still more preferably from about 2 to about 3. Nonlimiting examples of these cationic emulsifiers include stearamidopropyl PG-dimonium chloride phosphate, behenamidopropyl PG dimonium chloride, stearamidopropyl ethyldimonium ethosulfate, stearamidopropyl dimethyl (myristyl acetate) ammonium chloride, stearamidopropyl dimethyl cetearyl ammonium tosylate, stearamidopropyl dimethyl ammonium chloride, stearamidopropyl dimethyl ammonium lactate, and mixtures thereof. Especially preferred is behenamidopropyl PG dimonium chloride.

Nonlimiting examples of quaternary ammonium salt cationic surfactants include those selected from cetyl ammonium chloride, cetyl ammonium bromide, lauryl ammonium chloride, lauryl ammonium bromide, stearyl ammonium chloride, stearyl ammonium bromide, cetyl dimethyl ammonium chloride, cetyl dimethyl ammonium bromide, lauryl dimethyl ammonium chloride, lauryl dimethyl ammonium bromide, stearyl dimethyl ammonium chloride, stearyl dimethyl ammonium bromide, cetyl trimethyl ammonium chloride, cetyl trimethyl ammonium bromide, lauryl trimethyl ammonium chloride, lauryl trimethyl ammonium bromide, stearyl trimethyl ammonium chloride, stearyl trimethyl ammonium bromide, lauryl dimethyl ammonium chloride, stearyl dimethyl cetyl ditallow dimethyl ammonium chloride, dicetyl ammonium chloride, dicetyl ammonium bromide, dilauryl ammonium chloride, dilauryl ammonium bromide, distearyl ammonium chloride, distearyl ammonium bromide, dicetyl methyl ammonium chloride, dicetyl methyl ammonium bromide, dilauryl methyl ammonium chloride, dilauryl methyl ammonium bromide, distearyl methyl ammonium chloride, distearyl methyl ammonium bromide, and mixtures thereof. Additional quaternary ammonium salts include those wherein the C_{12} to C_{30} alkyl carbon chain is derived from a tallow fatty acid or from a coconut fatty acid. The term "tallow" refers to an alkyl group derived from tallow fatty acids (usually hydrogenated tallow fatty acids), which generally have mixtures of alkyl chains in the C_{16} to C_{18} range. The term "coconut" refers to an alkyl group derived from a coconut fatty acid, which generally have mixtures of alkyl chains in the C_{12} to C_{14} range. Examples of quaternary ammonium salts

derived from these tallow and coconut sources include ditallow dimethyl ammonium chloride, ditallow dimethyl ammonium methyl sulfate, di(hydrogenated tallow) dimethyl ammonium chloride, di(hydrogenated tallow) dimethyl ammonium acetate, ditallow dipropyl ammonium phosphate, ditallow dimethyl ammonium nitrate, di(coconutalkyl)dimethyl ammonium chloride, di(coconutalkyl)dimethyl ammonium bromide, tallow ammonium chloride, coconut ammonium chloride, stearamidopropyl PG-dimonium chloride phosphate, stearamidopropyl ethyldimonium ethosulfate, stearamidopropyl dimethyl (myristyl acetate) ammonium chloride, stearamidopropyl dimethyl cetearyl ammonium tosylate, stearamidopropyl dimethyl ammonium chloride, stearamidopropyl dimethyl ammonium lactate, and mixtures thereof. An example of a quaternary ammonium compound having an alkyl group with an ester linkage is ditallowyl oxyethyl dimethyl ammonium chloride.

More preferred cationic surfactants are those selected from behenamidopropyl PG dimonium chloride, dilauryl dimethyl ammonium chloride, distearyl dimethyl ammonium chloride, dimyristyl dimethyl ammonium chloride, dipalmityl dimethyl ammonium chloride, distearyl dimethyl ammonium chloride, stearamidopropyl PG-dimonium chloride phosphate, stearamidopropyl ethyldiammonium ethosulfate, stearamidopropyl dimethyl (myristyl acetate) ammonium chloride, stearamidopropyl dimethyl cetearyl ammonium tosylate, stearamidopropyl dimethyl ammonium chloride, stearamidopropyl dimethyl ammonium lactate, and mixtures thereof.

Still more preferred cationic surfactants are those selected from behenamidopropyl PG dimonium chloride, dilauryl dimethyl ammonium chloride, distearyl dimethyl ammonium chloride, dimyristyl dimethyl ammonium chloride, dipalmityl dimethyl ammonium chloride, and mixtures thereof.

A preferred combination of cationic surfactant and structuring agent is behenamidopropyl PG dimonium chloride and/or behenyl alcohol, wherein the ratio is preferably optimized to maintained to enhance physical and chemical stability, especially when such a combination contains ionic and/or highly polar solvents. This combination is especially useful for delivery of sunscreening agents such as zinc oxide and octyl methoxycinnamate.

A wide variety of anionic surfactants are also useful herein. See, e.g., U.S. Patent No. 3,929,678, to Laughlin et al., issued December 30, 1975, which is incorporated herein by reference in its entirety. Nonlimiting examples of anionic surfactants include the alkoyl isethionates, and the alkyl and alkyl ether sulfates. The alkoyl isethionates typically have the formula $RCO\text{-}OCH_2CH_2SO_3M$ wherein R is alkyl or alkenyl of from about 10 to about 30

carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium and triethanolamine. Nonlimiting examples of these isethionates include those alkoyl isethionates selected from ammonium cocoyl isethionate, sodium cocoyl isethionate, sodium lauroyl isethionate, sodium stearoyl isethionate, and mixtures thereof.

The alkyl and alkyl ether sulfates typically have the respective formulae $ROSO_3M$ and $RO(C_2H_4O)_xSO_3M$, wherein R is alkyl or alkenyl of from about 10 to about 30 carbon atoms, x is from about 1 to about 10, and M is a water-soluble cation such as ammonium, sodium, potassium and triethanolamine. Another suitable class of anionic surfactants are the water-soluble salts of the organic, sulfuric acid reaction products of the general formula:

$$R_1\text{--}SO_3\text{--}M$$

wherein R_1 is chosen from the group including a straight or branched chain, saturated aliphatic hydrocarbon radical having from about 8 to about 24, preferably about 10 to about 16, carbon atoms; and M is a cation. Still other anionic synthetic surfactants include the class designated as succinamates, olefin sulfonates having about 12 to about 24 carbon atoms, and β-alkyloxy alkane sulfonates. Examples of these materials are sodium lauryl sulfate and ammonium lauryl sulfate.

Other anionic materials useful herein are soaps (i.e. alkali metal salts, e.g., sodium or potassium salts) of fatty acids, typically having from about 8 to about 24 carbon atoms, preferably from about 10 to about 20 carbon atoms. The fatty acids used in making the soaps can be obtained from natural sources such as, for instance, plant or animal-derived glycerides (e.g., palm oil, coconut oil, soybean oil, castor oil, tallow, lard, etc.) The fatty acids can also be synthetically prepared. Soaps are described in more detail in U.S. Patent No. 4,557,853.

Amphoteric and zwitterionic surfactants are also useful herein. Examples of amphoteric and zwitterionic surfactants which can be used in the compositions of the present invention are those which are broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be straight or branched chain and wherein one of the aliphatic substituents contains from about 8 to about 22 carbon atoms (preferably C_8 - C_{18}) and one contains an anionic water solubilizing group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Examples are alkyl imino acetates, and iminodialkanoates and aminoalkanoates of the formulas $RN[CH_2)_mCO_2M]_2$ and $RNH(CH_2)_mCO_2M$ wherein m is from 1 to 4, R is a C_8-C_{22} alkyl or alkenyl, and M is H, alkali metal, alkaline earth metal ammonium, or alkanolammonium. Also included are imidazolinium and ammonium derivatives. Specific

examples of suitable amphoteric surfactants include sodium 3-dodecyl-aminopropionate, sodium 3-dodecylaminopropane sulfonate, N-alkyltaurines such as the one prepared by reacting dodecylamine with sodium isethionate according to the teaching of U.S. Patent 2,658,072 which is incorporated herein by reference in its entirety; N-higher alkyl aspartic acids such as those produced according to the teaching of U.S. Patent 2,438,091 which is incorporated herein by reference in its entirety; and the products sold under the trade name "Miranol" and described in U.S. Patent 2,528,378, which is incorporated herein by reference in its entirety. Other examples of useful amphoterics include phosphates, such as coamidopropyl PG-dimonium chloride phosphate (commercially available as Monaquat PTC, from Mona Corp.).

Other amphoteric or zwitterionic surfactants useful herein include betaines. Examples of betaines include the higher alkyl betaines, such as coco dimethyl carboxymethyl betaine, lauryl dimethyl carboxymethyl betaine, lauryl dimethyl alphacarboxyethyl betaine, cetyl dimethyl carboxymethyl betaine, cetyl dimethyl betaine (available as Lonzaine 16SP from Lonza Corp.), lauryl bis-(2-hydroxyethyl) carboxymethyl betaine, stearyl bis-(2-hydroxypropyl) carboxymethyl betaine, oleyl dimethyl gamma-carboxypropyl betaine, lauryl bis-(2-hydroxypropyl)alpha-carboxyethyl betaine, coco dimethyl sulfopropyl betaine, stearyl dimethyl sulfopropyl betaine, lauryl dimethyl sulfoethyl betaine, lauryl bis-(2-hydroxyethyl) sulfopropyl betaine, and amidobetaines and amidosulfobetaines (wherein the $RCONH(CH_2)_3$ radical is attached to the nitrogen atom of the betaine), oleyl betaine (available as amphoteric Velvetex OLB-50 from Henkel), and cocamidopropyl betaine (available as Velvetex BK-35 and BA-35 from Henkel).

Other useful amphoteric and zwitterionic surfactants include the sultaines and hydroxysultaines such as cocamidopropyl hydroxysultaine (available as Mirataine CBS from Rhone-Poulenc), and the alkanoyl sarcosinates corresponding to the formula $RCON(CH_3)CH_2CH_2CO_2M$ wherein R is alkyl or alkenyl of about 10 to about 20 carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium and trialkanolamine (e.g., triethanolamine), a preferred example of which is sodium lauroyl sarcosinate.

(3) Water

A preferred oil-in-water emulsion form may contain from about 25% to about 98%, preferably from about 40% to about 95%, more preferably from about 50% to about 90% water by weight of the composition.

The hydrophobic phase is dispersed in the continuous aqueous phase. The hydrophobic phase may contain water insoluble or partially soluble materials such as are known in the art, including but not limited to the silicones described herein in reference to silicone-in-water emulsions, and other oils and lipids such as described above in reference to emulsions.

Compositions of this invention useful for cleansing ("cleansers") are formulated with a suitable delivery system, e.g., as described above, and preferably contain, from about 1% to about 90%, more preferably from about 5% to about 10%, of a dermatologically acceptable surfactant. The surfactant is suitably selected from anionic, nonionic, zwitterionic, amphoteric and ampholytic surfactants, as well as mixtures of these surfactants. Such surfactants are well known to those skilled in the detergency art. Nonlimiting examples of possible surfactants include isoceteth-20, sodium methyl cocoyl taurate, sodium methyl oleoyl taurate, and sodium lauryl sulfate. See U.S. Patent No. 4,800,197, to Kowcz et al., issued January 24, 1989, which is incorporated herein by reference in its entirety, for exemplary surfactants useful herein. Examples of a broad variety of additional surfactants useful herein are described in McCutcheon's Detergents and Emulsifiers, North American Edition (1986), published by Allured Publishing Corporation. The cleansing compositions can optionally contain, at their art-established levels, other materials which are conventionally used in cleansing compositions.

The physical form of the cleansing compositions is not critical. The compositions can be, for example, formulated as toilet bars, liquids, shampoos, bath gels, hair conditioners, hair tonics, pastes, or mousses. Rinse-off cleansing compositions, such as shampoos, require a delivery system adequate to deposit sufficient levels of actives on the skin and scalp. A preferred delivery system involves the use of insoluble complexes. For a more complete disclosure of such delivery systems, see U.S. Patent 4,835,148, Barford et al., issued May 30, 1989.

OPTIONAL INGREDIENTS

The compositions of the present invention may contain one or more additional skin care actives. In a preferred embodiment, where the composition is to be in contact with human keratinous tissue, the additional components should be suitable for application to keratinous tissue, that is, when incorporated into the composition they are suitable for use in contact with human keratinous tissue without undue toxicity, incompatibility, instability, allergic response, and the like within the scope of sound medical judgment.

The *CTFA Cosmetic Ingredient Handbook*, Second Edition (1992) describes a wide variety of nonlimiting cosmetic and pharmaceutical ingredients commonly used in the skin care

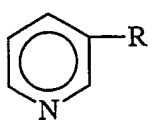
industry, which are suitable for use in the compositions of the present invention. Examples of these ingredient classes include: abrasives, absorbents, aesthetic components such as fragrances, pigments, colorings/colorants, essential oils, skin sensates, astringents, etc. (e.g., clove oil, menthol, camphor, eucalyptus oil, eugenol, menthyl lactate, witch hazel distillate), anti-acne agents, anti-caking agents, antifoaming agents, antioxidants, binders, biological additives, buffering agents, bulking agents, chelating agents, chemical additives, cosmetic astringents, cosmetic biocides, denaturants, drug astringents, external analgesics, film formers or materials, e.g., polymers, for aiding the film-forming properties and substantivity of the composition (e.g., copolymer of eicosene and vinyl pyrrolidone), opacifying agents, pH adjusters, preservatives, propellants, reducing agents, sequestrants, skin bleaching and lightening agents (e.g., hydroquinone, kojic acid, ascorbic acid, ascorbyl glucosamine), skin-conditioning agents (e.g., humectants, including miscellaneous and occlusive), skin soothing and/or healing agents (e.g., panthenol and derivatives (e.g., ethyl panthenol), aloe vera, pantothenic acid and its derivatives, allantoin, bisabolol, and dipotassium glycyrrhizinate), skin treating agents, thickeners, and vitamins and derivatives thereof.

In any embodiment of the present invention, however, the actives useful herein can be categorized by the benefit they provide or by their postulated mode of action. However, it is to be understood that the actives useful herein can in some instances provide more than one benefit or operate via more than one mode of action. Therefore, classifications herein are made for the sake of convenience and are not intended to limit the active to that particular application or applications listed.

Vitamin B_3 compound

The compositions of the present invention may also include, in some embodiments, an additional vitamin B_3 compound (other than niacinamide). When present, the composition preferably includes from about 0.01% to about 50%, more preferably from about 0.1% to about 10%, even more preferably from about 0.5% to about 10%, and still more preferably from about 1% to about 5%, by weight of the composition, of the vitamin B_3 compound.

As used herein, "vitamin B_3 compound" means a compound having the formula:



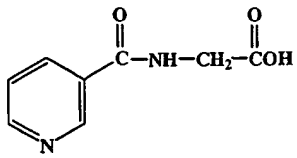
wherein R is, - COOH (i.e., nicotinic acid) or - CH_2OH (i.e., nicotinyl alcohol); derivatives thereof; and salts of any of the foregoing.

Exemplary derivatives of the foregoing vitamin B_3 compounds include nicotinic acid esters, including non-vasodilating esters of nicotinic acid, nicotinyl amino acids, and nicotinyl alcohol esters of carboxylic acids.

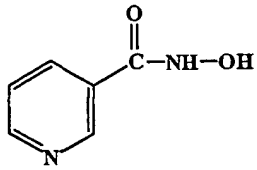
Suitable esters of nicotinic acid include nicotinic acid esters of C_1-C_{22}, preferably C_1-C_{16}, more preferably C_1-C_6 alcohols. The alcohols are suitably straight-chain or branched chain, cyclic or acyclic, saturated or unsaturated (including aromatic), and substituted or unsubstituted. The esters are preferably non-rubifacient. As used herein, "non-rubifacient" means that the ester does not commonly yield a visible flushing response after application to the skin in the subject compositions (the majority of the general population would not experience a visible flushing response, although such compounds may cause vasodilation not visible to the naked eye). Alternatively, a nicotinic acid material which is rubifacient at higher doses could be used at a lower dose to reduce the rubifacient effect. Non-rubifacient esters of nicotinic acid include tocopherol nicotinate and inositol hexanicotinate; tocopherol nicotinate is preferred.

Other derivatives of the vitamin B_3 compound are derivatives of niacinamide resulting from substitution of one or more of the amide group hydrogens. Nonlimiting examples of derivatives of niacinamide useful herein include nicotinyl amino acids, derived, for example, from the reaction of an activated nicotinic acid compound (e.g., nicotinic acid azide or nicotinyl chloride) with an amino acid, and nicotinyl alcohol esters of organic carboxylic acids (e.g., C1 - C18). Specific examples of such derivatives include nicotinuric acid and nicotinyl hydroxamic acid, which have the following chemical structures:

nicotinuric acid:



nicotinyl hydroxamic acid:



Exemplary nicotinyl alcohol esters include nicotinyl alcohol esters of the carboxylic acids salicylic acid, acetic acid, glycolic acid, palmitic acid and the like. Other non-limiting examples of vitamin B_3 compounds useful herein are 2-chloronicotinamide, 6-aminonicotinamide, 6-methylnicotinamide, n-methyl-nicotinamide, n,n-diethylnicotinamide, n-(hydroxymethyl)-nicotinamide, quinolinic acid imide, nicotinanilide, n-benzylnicotinamide, n-ethylnicotinamide, nifenazone, nicotinaldehyde, isonicotinic acid, methyl isonicotinic acid, thionicotinamide, nialamide, 1-(3-pyridylmethyl) urea, 2-mercaptonicotinic acid, nicomol, and niaprazine.

Examples of the above vitamin B_3 compounds are well known in the art and are commercially available from a number of sources, e.g., the Sigma Chemical Company (St. Louis, MO); ICN Biomedicals, Inc. (Irvin, CA) and Aldrich Chemical Company (Milwaukee, WI).

When used, salts, derivatives, and salt derivatives of niacinamide are preferably those having substantially the same efficacy as niacinamide in the methods of regulating skin condition described herein.

Salts of the vitamin B_3 compound are also useful herein. Nonlimiting examples of salts of the vitamin B_3 compound useful herein include organic or inorganic salts, such as inorganic salts with anionic inorganic species (e.g., chloride, bromide, iodide, carbonate, preferably chloride), and organic carboxylic acid salts (including mono-, di- and tri- C1 - C18 carboxylic acid salts, e.g., acetate, salicylate, glycolate, lactate, malate, citrate, preferably monocarboxylic acid salts such as acetate). These and other salts of the vitamin B_3 compound can be readily prepared by the skilled artisan, for example, as described by W. Wenner,. "The Reaction of L-Ascorbic and D-Isoascorbic Acid with Nicotinic Acid and Its Amide", J. Organic Chemistry, VOL. 14, 22-26 (1949), which is incorporated herein by reference. Wenner describes the synthesis of the ascorbic acid salt of niacinamide.

Preferably, the ring nitrogen of the vitamin B_3 compound is substantially chemically free (e.g., unbound and/or unhindered), or after delivery to the skin becomes substantially chemically free ("chemically free" is hereinafter alternatively referred to as "uncomplexed").

Preferably the vitamin B_3 compound is substantially uncomplexed in the composition prior to delivery to the skin. Preferably the vitamin B_3 compound is essentially free of the salt form. The vitamin B_3 compound may be included as the substantially pure material, or as an

extract obtained by suitable physical and/or chemical isolation from natural (e.g., plant) sources. The vitamin B_3 compound is preferably substantially pure, more preferably essentially pure.

Phytantriol

The topical compositions of the present invention may, in some embodiments, contain a safe and effective amount of phytantriol. Phytantriol is the common name for the chemical known as 3,7,11,15,tetramethylhexadecane-1,2,3,-triol. Phytantriol is commercially available from BASF (1609 Biddle Avenue, Whyandotte, MI). For example, phytantriol is useful as a spider vessel/ red blotchiness repair agent, a dark circle/puffy eye repair agent, sallowness repair agent, a sagging repair agent, an anti-itch agent, a skin thickening agent, a pore reduction agent, oil/shine reduction agent, a post-inflammatory hyperpigmentation repair agent, wound treating agent, an anti-cellulite agent, and regulating skin texture, including wrinkles and fine lines.

When included in compositions of the present invention, the phytantriol preferably is included in an amount from about 0.001% to about 50% by weight of the composition, more preferably from about 0.01% to about 20%, even more preferably from about 0.1% to about 15%, even more preferably from about 0.2% to about 10%, still more preferably from about 0.5% to about 10%, and still more preferably from about 1% to about 5%.

Farnesol

The topical compositions of the present invention may, in some embodiments, contain a safe and effective amount of farnesol. Farnesol is a naturally occurring substance which is believed to act as a precursor and/or intermediate in the biosynthesis of squalene and sterols, especially cholesterol. Farnesol is also involved in protein modification and regulation (e.g., farnesylation of proteins), and there is a cell nuclear receptor which is responsive to farnesol.

Chemically, farnesol is [2E,6E]-3,7,11-trimethyl-2,6,10-dodecatrien-1-ol and as used herein "farnesol" includes isomers and tautomers of such. Farnesol is commercially available, e.g., under the names farnesol (a mixture of isomers from Dragoco, 10 Gordon Drive, Totowa, New Jersey) and trans-trans-farnesol (Sigma Chemical Company, P. O. Box 14508, St. Louis, Missouri).

When present in the compositions of the present invention, the composition preferably contains from about 0.001% to about 50%, by weight of the composition, more preferably from about 0.01% to about 20%, even more preferably from about 0.1% to about 15%, even more preferably from about 0.1% to about 10%, still more preferably from about 0.5% to about 5%, and still more preferably from about 1% to about 5% of farnesol.

Desquamation Actives

A safe and effective amount of a desquamation active may be added to the compositions of the present invention, preferably from about 0.1% to about 10%, more preferably from about 0.2% to about 5%, even more preferably from about 0.5% to about 4%, by weight of the composition. Desquamation actives enhance the skin appearance benefits of the present invention. For example, the desquamation actives tend to improve the texture of the skin (e.g., smoothness). One desquamation system that is suitable for use herein contains sulfhydryl compounds and zwitterionic surfactants and is described in U.S. Patent No. 5,681,852, to Bissett, incorporated herein by reference. Another desquamation system that is suitable for use herein contains salicylic acid and zwitterionic surfactants and is described in U.S. Patent No. 5,652,228 to Bissett, incorporated herein by reference. Zwitterionic surfactants such as described in these applications are also useful as desquamatory agents herein, with cetyl betaine being particularly preferred.

Anti-Acne Actives

The compositions of the present invention may contain a safe and effective amount of one or more anti-acne actives. Examples of useful anti-acne actives include resorcinol, sulfur, salicylic acid, benzoyl peroxide, erythromycin, zinc, etc. Further examples of suitable anti-acne actives are described in further detail in U. S. Patent No. 5,607,980, issued to McAtee et al, on March 4, 1997.

Anti-Wrinkle Actives/Anti-Atrophy Actives

The compositions of the present invention may further contain a safe and effective amount of one or more anti-wrinkle actives or anti-atrophy actives. Exemplary anti-wrinkle/anti-atrophy actives suitable for use in the compositions of the present invention include sulfur-containing D and L amino acids and their derivatives and salts, particularly the N-acetyl derivatives, a preferred example of which is N-acetyl-L-cysteine; thiols, e.g. ethane thiol; hydroxy acids (e.g., alpha-hydroxy acids such as lactic acid and glycolic acid or beta-hydroxy acids such as salicylic acid and salicylic acid derivatives such as the octanoyl derivative), phytic acid, lipoic acid; lysophosphatidic acid, skin peel agents (e.g., phenol and the like), and retinoids which enhance the keratinous tissue appearance benefits of the present invention, especially in regulating keratinous tissue condition, e.g., skin condition.

a) Retinoids

The compositions of the present invention may also contain a retinoid. As used herein, "retinoid" includes all natural and/or synthetic analogs of Vitamin A or retinol-like compounds which possess the biological activity of Vitamin A in the skin as well as the geometric isomers

and stereoisomers of these compounds. The retinoid is preferably retinol, retinol esters (e.g., C_2 - C_{22} alkyl esters of retinol, including retinyl palmitate, retinyl acetate, retinyl propionate), retinal, and/or retinoic acid (including all-trans retinoic acid and/or 13-cis-retinoic acid), more preferably retinoids other than retinoic acid. These compounds are well known in the art and are commercially available from a number of sources, e.g., Sigma Chemical Company (St. Louis, MO), and Boerhinger Mannheim (Indianapolis, IN). Other retinoids which are useful herein are described in U.S. Patent Nos. 4,677,120, issued Jun. 30, 1987 to Parish et al.; 4,885,311, issued Dec. 5, 1989 to Parish et al.; 5,049,584, issued Sep. 17, 1991 to Purcell et al.; 5,124,356, issued Jun. 23, 1992 to Purcell et al.; and Reissue 34,075, issued Sep. 22, 1992 to Purcell et al.. Other suitable retinoids are tocopheryl-retinoate [tocopherol ester of retinoic acid (trans- or cis-), adapalene {6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid}, and tazarotene (ethyl 6-[2-(4,4-dimethylthiochroman-6-yl)-ethynyl]nicotinate). Preferred retinoids are retinol, retinyl palmitate, retinyl acetate, retinyl propionate, retinal and combinations thereof.

The retinoid may be included as the substantially pure material, or as an extract obtained by suitable physical and/or chemical isolation from natural (e.g., plant) sources. The retinoid is preferably substantially pure, more preferably essentially pure.

The compositions of this invention may contain a safe and effective amount of the retinoid, such that the resultant composition is safe and effective for regulating keratinous tissue condition, preferably for regulating visible and/or tactile discontinuities in skin, more preferably for regulating signs of skin aging, even more preferably for regulating visible and/or tactile discontinuities in skin texture associated with skin aging. The compositions preferably contain from or about 0.005% to or about 2%, more preferably 0.01% to or about 2%, retinoid. Retinol is preferably used in an amount of from or about 0.01% to or about 0.15%; retinol esters (e.g. retinyl propionate, retinyl palmitate) are preferably used in an amount of from or about 0.01% to or about 2% (e.g., about 1%); retinoic acids are preferably used in an amount of from or about 0.01% to or about 0.25%; tocopheryl-retinoate, adapalene, and tazarotene are preferably used in an amount of from or about 0.01% to or about 2%.

b) Hydroxy Acids

The compositions of the present invention may contain a safe and effective amount of a Hydroxy Acid. Preferred hydroxy acids for use in the compositions of the present invention include salicylic acid and salicylic acid derivatives. When present in the compositions of the present invention, salicylic acid is preferably used in an amount of from about 0.01% to about 50%, more preferably from about 0.1% to about 20%, even more preferably from about 0.1% to

about 10%, still more preferably from about 0.5% to about 5%, and still more preferably from about 0.5% to about 2%.

Anti-Oxidants/Radical Scavengers

The compositions of the present invention may include a safe and effective amount of an anti-oxidant/radical scavenger. The anti-oxidant/radical scavenger is especially useful for providing protection against UV radiation which can cause increased scaling or texture changes in the stratum corneum and against other environmental agents which can cause skin damage.

A safe and effective amount of an anti-oxidant/radical scavenger may be added to the compositions of the subject invention, preferably from about 0.1% to about 10%, more preferably from about 1% to about 5%, of the composition.

Anti-oxidants/radical scavengers such as ascorbic acid (vitamin C) and its salts, ascorbyl esters of fatty acids, ascorbic acid derivatives (e.g., magnesium ascorbyl phosphate, sodium ascorbyl phosphate, ascorbyl sorbate), tocopherol (vitamin E), tocopherol sorbate, tocopherol acetate, other esters of tocopherol, butylated hydroxy benzoic acids and their salts, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid (commercially available under the tradename Trolox^{R}), gallic acid and its alkyl esters, especially propyl gallate, uric acid and its salts and alkyl esters, sorbic acid and its salts, lipoic acid, amines (e.g., N,N-diethylhydroxylamine, amino-guanidine), sulfhydryl compounds (e.g., glutathione), dihydroxy fumaric acid and its salts, lycine pidolate, arginine pilolate, nordihydroguaiaretic acid, bioflavonoids, curcumin, lysine, methionine, proline, superoxide dismutase, silymarin, tea extracts, grape skin/seed extracts, melanin, and rosemary extracts may be used. Preferred anti-oxidants/radical scavengers are selected from tocopherol acetate and other esters of tocopherol, more preferably tocopherol acetate. The use of tocopherol sorbate in topical compositions and applicable to the present invention is described in U.S. Patent No. 4,847,071, issued on July 11, 1989 to Donald L. Bissett, Rodney D. Bush and Ranjit Chatterjee.

Chelators

The compositions of the present invention may also contain a safe and effective amount of a chelator or chelating agent. As used herein, "chelator" or "chelating agent" means an active agent capable of removing a metal ion from a system by forming a complex so that the metal ion cannot readily participate in or catalyze chemical reactions. The inclusion of a chelating agent is especially useful for providing protection against UV radiation which can contribute to excessive scaling or skin texture changes and against other environmental agents which can cause skin damage.

A safe and effective amount of a chelating agent may be added to the compositions of the subject invention, preferably from about 0.1% to about 10%, more preferably from about 1% to about 5%, of the composition. Exemplary chelators that are useful herein are disclosed in U.S. Patent No. 5,487,884, issued 1/30/96 to Bissett et al.; International Publication No. 91/16035, Bush et al., published 10/31/95; and International Publication No. 91/16034, Bush et al., published 10/31/95. Preferred chelators useful in compositions of the subject invention are furildioxime, furilmonoxime, and derivatives thereof.

Flavonoids

The compositions of the present invention may optionally contain a flavonoid compound. Flavonoids are broadly disclosed in U.S. Patents 5,686,082 and 5,686,367, both of which are herein incorporated by reference. Flavonoids suitable for use in the present invention are flavanones selected from unsubstituted flavanones, mono-substituted flavanones, and mixtures thereof; chalcones selected from unsubstituted chalcones, mono-substituted chalcones, di-substituted chalcones, tri-substituted chalcones, and mixtures thereof; flavones selected from unsubstituted flavones, mono-substituted flavones, di-substituted flavones, and mixtures thereof; one or more isoflavones; coumarins selected from unsubstituted coumarins, mono-substituted coumarins, di-substituted coumarins, and mixtures thereof; chromones selected from unsubstituted chromones, mono-substituted chromones, di-substituted chromones, and mixtures thereof; one or more dicoumarols; one or more chromanones; one or more chromanols; isomers (e.g., cis/trans isomers) thereof; and mixtures thereof. By the term "substituted" as used herein means flavonoids wherein one or more hydrogen atom of the flavonoid has been independently replaced with hydroxyl, C1-C8 alkyl, C1-C4 alkoxyl, O-glycoside, and the like or a mixture of these substituents.

Examples of suitable flavonoids include, but are not limited to, unsubstituted flavanone, mono-hydroxy flavanones (e.g., 2'-hydroxy flavanone, 6-hydroxy flavanone, 7-hydroxy flavanone, etc.), mono-alkoxy flavanones (e.g., 5-methoxy flavanone, 6-methoxy flavanone, 7-methoxy flavanone, 4'-methoxy flavanone, etc.), unsubstituted chalcone (especially unsubstituted trans-chalcone), mono-hydroxy chalcones (e.g., 2'-hydroxy chalcone, 4'-hydroxy chalcone, etc.), di-hydroxy chalcones (e.g., 2',4-dihydroxy chalcone, 2',4'-dihydroxy chalcone, 2,2'-dihydroxy chalcone, 2',3-dihydroxy chalcone, 2',5'-dihydroxy chalcone, etc.), and tri-hydroxy chalcones (e.g., 2',3',4'-trihydroxy chalcone, 4,2',4'-trihydroxy chalcone, 2,2',4'-trihydroxy chalcone, etc.), unsubstituted flavone, 7,2'-dihydroxy flavone, 3',4'-dihydroxy naphthoflavone, 4'-hydroxy flavone, 5,6-benzoflavone, and 7,8-benzoflavone, unsubstituted isoflavone, daidzein (7,4'-

dihydroxy isoflavone), 5,7-dihydroxy-4'-methoxy isoflavone, soy isoflavones (a mixture extracted from soy), unsubstituted coumarin, 4-hydroxy coumarin, 7-hydroxy coumarin, 6-hydroxy-4-methyl coumarin, unsubstituted chromone, 3-formyl chromone, 3-formyl-6-isopropyl chromone, unsubstituted dicoumarol, unsubstituted chromanone, unsubstituted chromanol, and mixtures thereof..

Preferred for use herein are unsubstituted flavanone, methoxy flavanones, unsubstituted chalcone, 2',4-dihydroxy chalcone, and mixtures thereof. More preferred are unsubstituted flavanone, unsubstituted chalcone (especially the trans isomer), and mixtures thereof.

They can be synthetic materials or obtained as extracts from natural sources (e.g., plants). The naturally sourced material can also further be derivatized (e.g., an ester or ether derivative prepared following extraction from a natural source). Flavonoid compounds useful herein are commercially available from a number of sources, e.g., Indofine Chemical Company, Inc. (Somerville, New Jersey), Steraloids, Inc. (Wilton, New Hampshire), and Aldrich Chemical Company, Inc. (Milwaukee, Wisconsin).

Mixtures of the above flavonoid compounds may also be used.

The herein described flavonoid compounds are preferably present in the instant invention at concentrations of from about 0.01% to about 20%, more preferably from about 0.1% to about 10% , and still more preferably from about 0.5% to about 5%.

Anti-Inflammatory Agents

A safe and effective amount of an anti-inflammatory agent may be added to the compositions of the present invention, preferably from about 0.1% to about 10%, more preferably from about 0.5% to about 5%, of the composition. The anti-inflammatory agent enhances the skin appearance benefits of the present invention, e.g., such agents contribute to a more uniform and acceptable skin tone or color. The exact amount of anti-inflammatory agent to be used in the compositions will depend on the particular anti-inflammatory agent utilized since such agents vary widely in potency.

Steroidal anti-inflammatory agents, including but not limited to, corticosteroids such as hydrocortisone, hydroxyltriamcinolone, alpha-methyl dexamethasone, dexamethasone-phosphate, beclomethasone dipropionates, clobetasol valerate, desonide, desoxymethasone, desoxycorticosterone acetate, dexamethasone, dichlorisone, diflorasone diacetate, diflucortolone valerate, fluadrenolone, fluclorolone acetonide, fludrocortisone, flumethasone pivalate, fluosinolone acetonide, fluocinonide, flucortine butylesters, fluocortolone, fluprednidene (fluprednylidene) acetate, flurandrenolone, halcinonide, hydrocortisone acetate, hydrocortisone

butyrate, methylprednisolone, triamcinolone acetonide, cortisone, cortodoxone, flucetonide, fludrocortisone, difluorosone diacetate, fluradrenolone, fludrocortisone, diflurosone diacetate, fluradrenolone acetonide, medrysone, amcinafel, amcinafide, betamethasone and the balance of its esters, chloroprednisone, chlorprednisone acetate, clocortelone, clescinolone, dichlorisone, diflurprednate, flucloronide, flunisolide, fluoromethalone, fluperolone, fluprednisolone, hydrocortisone valerate, hydrocortisone cyclopentylpropionate, hydrocortamate, meprednisone, paramethasone, prednisolone, prednisone, beclomethasone dipropionate, triamcinolone, and mixtures thereof may be used. The preferred steroidal anti-inflammatory for use is hydrocortisone.

A second class of anti-inflammatory agents which is useful in the compositions includes the nonsteroidal anti-inflammatory agents. The variety of compounds encompassed by this group are well-known to those skilled in the art. For detailed disclosure of the chemical structure, synthesis, side effects, etc. of non-steroidal anti-inflammatory agents, one may refer to standard texts, including Anti-inflammatory and Anti-Rheumatic Drugs, K. D. Rainsford, Vol. I-III, CRC Press, Boca Raton, (1985), and Anti-inflammatory Agents, Chemistry and Pharmacology, 1, R. A. Scherrer, et al., Academic Press, New York (1974).

Specific non-steroidal anti-inflammatory agents useful in the composition invention include, but are not limited to:

1) the oxicams, such as piroxicam, isoxicam, tenoxicam, sudoxicam, and CP-14,304;

2) the salicylates, such as aspirin, disalcid, benorylate, trilisate, safapryn, solprin, diflunisal, and fendosal;

3) the acetic acid derivatives, such as diclofenac, fenclofenac, indomethacin, sulindac, tolmetin, isoxepac, furofenac, tiopinac, zidometacin, acematacin, fentiazac, zomepirac, clindanac, oxepinac, felbinac, and ketorolac;

4) the fenamates, such as mefenamic, meclofenamic, flufenamic, niflumic, and tolfenamic acids;

5) the propionic acid derivatives, such as ibuprofen, naproxen, benoxaprofen, flurbiprofen, ketoprofen, fenoprofen, fenbufen, indopropfen, pirprofen, carprofen, oxaprozin, pranoprofen, miroprofen, tioxaprofen, suprofen, alminoprofen, and tiaprofenic; and

6) the pyrazoles, such as phenylbutazone, oxyphenbutazone, feprazone, azapropazone, and trimethazone.

Mixtures of these non-steroidal anti-inflammatory agents may also be employed, as well as the dermatologically acceptable salts and esters of these agents. For example, etofenamate, a flufenamic acid derivative, is particularly useful for topical application. Of the nonsteroidal anti-inflammatory agents, ibuprofen, naproxen, flufenamic acid, etofenamate, aspirin, mefenamic acid, meclofenamic acid, piroxicam and felbinac are preferred; ibuprofen, naproxen, ketoprofen, etofenamate, aspirin and flufenamic acid are more preferred.

Finally, so-called "natural" anti-inflammatory agents are useful in methods of the present invention. Such agents may suitably be obtained as an extract by suitable physical and/or chemical isolation from natural sources (e.g., plants, fungi, by-products of microorganisms) or can be synthetically prepared. For example, candelilla wax, bisabolol (e.g., alpha bisabolol), aloe vera, plant sterols (e.g., phytosterol), Manjistha (extracted from plants in the genus Rubia, particularly Rubia Cordifolia), and Guggal (extracted from plants in the genus Commiphora, particularly Commiphora Mukul), kola extract, chamomile, red clover extract, and sea whip extract, may be used.

Additional anti-inflammatory agents useful herein include compounds of the Licorice (the plant genus/species Glycyrrhiza glabra) family, including glycyrrhetic acid, glycyrrhizic acid, and derivatives thereof (e.g., salts and esters). Suitable salts of the foregoing compounds include metal and ammonium salts. Suitable esters include C_2 - C_{24} saturated or unsaturated esters of the acids, preferably C_{10} - C_{24}, more preferably C_{16} - C_{24}. Specific examples of the foregoing include oil soluble licorice extract, the glycyrrhizic and glycyrrhetic acids themselves, monoammonium glycyrrhizinate, monopotassium glycyrrhizinate, dipotassium glycyrrhizinate, 1-beta-glycyrrhetic acid, stearyl glycyrrhetinate, and 3-stearyloxy-glycyrrhetinic acid, and disodium 3-succinyloxy-beta-glycyrrhetinate. Stearyl glycyrrhetinate is preferred.

Anti-Cellulite Agents

The compositions of the present invention may also contain a safe and effective amount of an anti-cellulite agent. Suitable agents may include, but are not limited to, xanthine compounds (e.g., caffeine, theophylline, theobromine, and aminophylline).

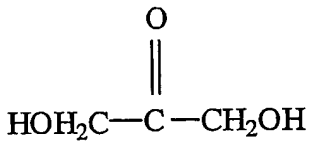
Topical Anesthetics

The compositions of the present invention may also contain a safe and effective amount of a topical anesthetic. Examples of topical anesthetic drugs include benzocaine, lidocaine, bupivacaine, chlorprocaine, dibucaine, etidocaine, mepivacaine, tetracaine, dyclonine, hexylcaine, procaine, cocaine, ketamine, pramoxine, phenol, and pharmaceutically acceptable salts thereof.

Tanning Actives

The compositions of the present invention may contain a tanning active. When present, it is preferable that the compositions contain from about 0.1% to about 20%, more preferably from about 2% to about 7%, and still more preferably from about 3% to about 6%, by weight of the composition, of dihydroxyacetone as an artificial tanning active.

Dihydroxyacetone, which is also known as DHA or 1,3-dihydroxy-2-propanone, is a white to off-white, crystalline powder. This material can be represented by the chemical formula $C_3H_6O_3$ and the following chemical structure.



The compound can exist as a mixture of monomers and dimers, with the dimers predominating in the solid crystalline state. Upon heating or melting, the dimers break down to yield the monomers. This conversion of the dimeric form to the monomeric form also occurs in aqueous solution. Dihydroxyacetone is also known to be more stable at acidic pH values. See The Merck Index, Tenth Edition, entry 3167, p. 463 (1983), and "Dihydroxyacetone for Cosmetics", E. Merck Technical Bulletin, 03-304 110, 319 897, 180 588.

Skin Lightening Agents

The compositions of the present invention may contain a skin lightening agent. When used, the compositions preferably contain from about 0.1% to about 10%, more preferably from about 0.2% to about 5%, also preferably from about 0.5% to about 2%, by weight of the composition, of a skin lightening agent. Suitable skin lightening agents include those known in the art, including kojic acid, arbutin, ascorbic acid and derivatives thereof (e.g sodium ascorbyl phosphate), and extracts (e.g., mulberry extract, placental extract). Skin lightening agents suitable for use herein also include those described in the PCT publication No. 95/34280, in the name of Hillebrand, corresponding to PCT Application No. U.S. 95/07432, filed 6/12/95; and co-pending U.S. Application No. 08/390,152 filed in the names of Kvalnes, Mitchell A. DeLong, Barton J. Bradbury, Curtis B. Motley, and John D. Carter, corresponding to PCT Publication No. 95/23780, published 9/8/95.

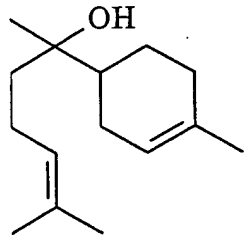
Skin Soothing and Skin Healing Actives

The compositions of the present invention may include a skin soothing or skin healing active. Skin soothing or skin healing actives suitable for use herein include panthenoic acid

derivatives (including panthenol, dexpanthenol, ethyl panthenol), aloe vera, allantoin, bisabolol, and dipotassium glycyrrhizinate. A safe and effective amount of a skin soothing or skin healing active may be added to the present composition, preferably, from about 0.1% to about 30%, more preferably from about 0.5% to about 20%, still more preferably from about 0.5% to about 10 %, by weight of the composition formed.

a) bisabolol

The topical compositions of the present invention may also contain a safe and effective amount of bisabolol. Bisabolol is a naturally occurring unsaturated monocyclic terpene alcohol having the following structure



It is the primary active component of chamomile extract/oil. Bisabolol can be synthetic (d,l - alpha-isomer or (+/-)-alpha-isomer) or natural ((-)-alpha-isomer) in origin and can be used as essentially pure compounds or mixtures of compounds (e.g., extracts from natural sources such as chamomile). The alpha form of bisabolol (á-bisabolol) is used in a variety of cosmetic products as a skin conditioning or soothing agent. As used herein, "bisabolol" includes chamomile extract or oil and any isomers and tautomers of such. Suitable bisabolol compounds are commercially available as a natural material from Dragoco (Totowa, New Jersey) under the product name alpha-bisabolol natural and as a synthetic material from Fluka (Milwaukee, Wisconsin) under the product name alpha-bisabolol.

In the compositions of the present invention, the composition preferably contains from about 0.001% to about 50%, by weight of the composition, more preferably from about 0.01% to about 20%, even more preferably from about 0.01% to about 15%, and still more preferably from about 0.1% to about 10%, of bisabolol, even more preferably from about 0.1% to about 5%.

Antimicrobial and Antifungal Actives

The compositions of the present invention may contain an antimicrobial or antifungal active. Such actives are capable of destroying microbes, preventing the development of microbes or preventing the pathogenic action of microbes. A safe and effective amount of an antimicrobial or antifungal active may be added to the present compositions, preferably, from about 0.001% to

about 10%, more preferably from about 0.01% to about 5%, and still more preferably from about 0.05% to about 2%.

Examples of antimicrobial and antifungal actives include ß-lactam drugs, quinolone drugs, ciprofloxacin, norfloxacin, tetracycline, erythromycin, amikacin, 2,4,4'-trichloro-2'-hydroxy diphenyl ether, 3,4,4'-trichlorobanilide, phenoxyethanol, phenoxy propanol, phenoxyisopropanol, doxycycline, capreomycin, chlorhexidine, chlortetracycline, oxytetracycline, clindamycin, ethambutol, hexamidine isethionate, metronidazole, pentamidine, gentamicin, kanamycin, lineomycin, methacycline, methenamine, minocycline, neomycin, netilmicin, paromomycin, streptomycin, tobramycin, miconazole, tetracycline hydrochloride, erythromycin, zinc erythromycin, erythromycin estolate, erythromycin stearate, amikacin sulfate, doxycycline hydrochloride, capreomycin sulfate, chlorhexidine gluconate, chlorhexidine hydrochloride, chlortetracycline hydrochloride, oxytetracycline hydrochloride, clindamycin hydrochloride, ethambutol hydrochloride, metronidazole hydrochloride, pentamidine hydrochloride, gentamicin sulfate, kanamycin sulfate, lineomycin hydrochloride, methacycline hydrochloride, methenamine hippurate, methenamine mandelate, minocycline hydrochloride, neomycin sulfate, netilmicin sulfate, paromomycin sulfate, streptomycin sulfate, tobramycin sulfate, miconazole hydrochloride, ketaconazole, amanfadine hydrochloride, amanfadine sulfate, octopirox, parachlorometa xylenol, nystatin, tolnaftate, zinc pyrithione and clotrimazole.

Sunscreen Actives

Exposure to ultraviolet light can result in excessive scaling and texture changes of the stratum corneum. Therefore, the compositions of the subject invention may optionally contain a sunscreen active. As used herein, "sunscreen active" includes both sunscreen agents and physical sunblocks. Suitable sunscreen actives may be organic or inorganic.

Inorganic sunscreens useful herein include the following metallic oxides; titanium dioxide having an average primary particle size of from about 15 nm to about 100 nm, zinc oxide having an average primary particle size of from about 15 nm to about 150 nm, zirconium oxide having an average primary particle size of from about 15 nm to about 150 nm, iron oxide having an average primary particle size of from about 15 nm to about 500nm, and mixtures thereof. When used herein, the inorganic sunscreens are present in the amount of from about 0.1% to about 20%, preferably from about 0.5% to about 10%, more preferably from about 1% to about 5%, by weight of the composition.

A wide variety of conventional organic sunscreen actives are suitable for use herein. Sagarin, et al., at Chapter VIII, pages 189 et seq., of Cosmetics Science and Technology (1972),

discloses numerous suitable actives. Specific suitable sunscreen actives include, for example: p-aminobenzoic acid, its salts and its derivatives (ethyl, isobutyl, glyceryl esters; p-dimethylaminobenzoic acid); anthranilates (i.e., o-amino-benzoates; methyl, menthyl, phenyl, benzyl, phenylethyl, linalyl, terpinyl, and cyclohexenyl esters); salicylates (amyl, phenyl, octyl, benzyl, menthyl, glyceryl, and di-pro-pyleneglycol esters); cinnamic acid derivatives (menthyl and benzyl esters, a-phenyl cinnamonitrile; butyl cinnamoyl pyruvate); dihydroxycinnamic acid derivatives (umbelliferone, methylumbelliferone, methylaceto-umbelliferone); trihydroxy-cinnamic acid derivatives (esculetin, methylesculetin, daphnetin, and the glucosides, esculin and daphnin); hydrocarbons (diphenylbutadiene, stilbene); dibenzalacetone and benzalacetophenone; naphtholsulfonates (sodium salts of 2-naphthol-3,6-disulfonic and of 2-naphthol-6,8-disulfonic acids); di-hydroxynaphthoic acid and its salts; o- and p-hydroxybiphenyldisulfonates; coumarin derivatives (7-hydroxy, 7-methyl, 3-phenyl); diazoles (2-acetyl-3-bromoindazole, phenyl benzoxazole, methyl naphthoxazole, various aryl benzothiazoles); quinine salts (bisulfate, sulfate, chloride, oleate, and tannate); quinoline derivatives (8-hydroxyquinoline salts, 2-phenylquinoline); hydroxy- or methoxy-substituted benzophenones; uric and violuric acids; tannic acid and its derivatives (e.g., hexaethylether); (butyl carbotol) (6-propyl piperonyl) ether; hydroquinone; benzophenones (oxybenzene, sulisobenzone, dioxybenzone, benzoresorcinol, 2,2',4,4'-tetrahydroxybenzophenone, 2,2'-dihydroxy-4,4'-dimethoxybenzophenone, octabenzone; 4-isopropyldibenzoylmethane; butylmethoxydibenzoylmethane; etocrylene; octocrylene; [3-(4'-methylbenzylidene bornan-2-one), terephthalylidene dicamphor sulfonic acid and 4-isopropyl-di-benzoylmethane.

Of these, 2-ethylhexyl-p-methoxycinnamate (commercially available as PARSOL MCX), 4,4'-t-butyl methoxydibenzoyl-methane (commercially available as PARSOL 1789), 2-hydroxy-4-methoxybenzophenone, octyldimethyl-p-aminobenzoic acid, digalloyltrioleate, 2,2-dihydroxy-4-methoxybenzophenone, ethyl-4-(bis(hydroxy-propyl))aminobenzoate, 2-ethylhexyl-2-cyano-3,3-diphenylacrylate, 2-ethylhexyl-salicylate, glyceryl-p-aminobenzoate, 3,3,5-tri-methylcyclohexylsalicylate, methylanthranilate, p-dimethyl-aminobenzoic acid or aminobenzoate, 2-ethylhexyl-p-dimethyl-amino-benzoate, 2-phenylbenzimidazole-5-sulfonic acid, 2-(p-dimethylaminophenyl)-5-sulfonicbenzoxazoic acid, octocrylene and mixtures of these compounds, are preferred.

More preferred organic sunscreen actives useful in the compositions useful in the subject invention are 2-ethylhexyl-p-methoxycinnamate, butylmethoxydibenzoyl-methane, 2-hydroxy-4-

methoxybenzo-phenone, 2-phenylbenzimidazole-5-sulfonic acid, octyldimethyl-p-aminobenzoic acid, octocrylene and mixtures thereof.

Also particularly useful in the compositions are sunscreen actives such as those disclosed in U.S. Patent No. 4,937,370 issued to Sabatelli on June 26, 1990, and U.S. Patent No. 4,999,186 issued to Sabatelli & Spirnak on March 12, 1991. The sunscreening agents disclosed therein have, in a single molecule, two distinct chromophore moieties which exhibit different ultra-violet radiation absorption spectra. One of the chromophore moieties absorbs predominantly in the UVB radiation range and the other absorbs strongly in the UVA radiation range.

Preferred members of this class of sunscreening agents are 4-N,N-(2-ethylhexyl)methyl-aminobenzoic acid ester of 2,4-dihydroxybenzophenone; N,N-di-(2-ethylhexyl)-4-aminobenzoic acid ester with 4-hydroxydibenzoylmethane; 4-N,N-(2-ethylhexyl)methyl-aminobenzoic acid ester with 4-hydroxydibenzoylmethane; 4-N,N-(2-ethylhexyl)methyl-aminobenzoic acid ester of 2-hydroxy-4-(2-hydroxyethoxy)benzophenone; 4-N,N-(2-ethylhexyl)-methylaminobenzoic acid ester of 4-(2-hydroxyethoxy)dibenzoylmethane; N,N-di-(2-ethylhexyl)-4-aminobenzoic acid ester of 2-hydroxy-4-(2-hydroxyethoxy)benzophenone; and N,N-di-(2-ethylhexyl)-4-aminobenzoic acid ester of 4-(2-hydroxyethoxy)dibenzoylmethane and mixtures thereof.

Especially preferred sunscreen actives include 4,4'-t-butylmethoxydibenzoylmethane, 2-ethylhexyl-p-methoxycinnamate, phenyl benzimidazole sulfonic acid, and octocrylene.

A safe and effective amount of the organic sunscreen active is used, typically from about 1% to about 20%, more typically from about 2% to about 10% by weight of the composition. Exact amounts will vary depending upon the sunscreen or sunscreens chosen and the desired Sun Protection Factor (SPF).

Particulate Material

The compositions of the present invention may, in some embodiments, contain a particulate material, preferably a metallic oxide. These particulates can be coated or uncoated, charged or uncharged. Charged particulate materials are disclosed in U.S. Patent No. 5,997,887, to Ha, et al., incorporated herein by reference. Particulate materials useful herein include; bismuth oxychloride, iron oxide, mica, mica treated with barium sulfate, titanium dioxide (TiO2), zinc oxide, zirconium oxide, silica, nylon, polyethylene, talc, styrene, polypropylene, ethylene/acrylic acid copolymer, sericite, aluminum oxide, silicone resin, barium sulfate, calcium carbonate, cellulose acetate, polymethyl methacrylate, and mixtures thereof.

Inorganic particulate materials, e.g., TiO2, ZnO, or ZrO2 are commercially available from a number of sources. One example of a suitable particulate material contains the material

available from U.S. Cosmetics (TRONOX TiO2 series, SAT-T CR837, a rutile TiO2). Preferably, particulate materials are present in the composition in levels of from about 0.01% to about 2%, more preferably from about 0.05% to about 1.5%, still more preferably from about 0.1% to about 1%, by weight of the composition. There are no specific limitations as to the pigment, colorant or filler powders used in the composition.

Preferred organic powders/fillers include, but are not limited, to polymeric particles chosen from the methylsilsesquioxane resin microspheres such as for example those sold by Toshiba silicone under the name Tospearl 145A; microspheres of polymethylmethacrylates such as those sold by Seppic under the name Micropearl M 100; the spherical particles of crosslinked polydimethylsiloxanes, especially such as those sold by Dow Corning Toray Silicone under the name Trefil E 506C or Trefil E 505C, sphericle particles of polyamide and more specifically Nylon 12, especially such as those sold by Atochem under the name Orgasol 2002D Nat C05, polystyerene microspheres such as for example those sold by Dyno Particles under the name Dynospheres, ethylene acrylate copolymer sold by Kobo under the name FloBead EA209 and mixtures thereof.

Also useful herein are pigment and/or dye encapsulates such nanocolorants from BASF and multi-layer interference pigments such as Sicopearls from BASF.

It is preferred that the pigments/powders are surface treated to provide added stability of color and ease of formulation. Hydrophobically treated pigments are more preferred, because they may be more easily dispersed in the delivery vehicle. In addition, it may be useful to treat the pigments with a material that is compatible with a silicone phase. Particularly useful hydrophobic pigment treatments for use in water-in-silicone emulsions include polysiloxane treatments such as those disclosed in U.S. Patent 5,143,722, incorporated herein by reference in its entirety. Also preferred are pigment/powders having a primary average particle size of from about 10 nm to about 100,000 nm, more preferably from about 50nm to about 5,000nm, most preferably from about 100nm to about 1000nm. Mixtures of the same or different pigment/powder having different particle sizes are also useful herein (e.g., incorporating a TiO2 having a primary particle size of from about 100 nm to about 400 nm with a TiO2 having a primary particle size of from about 10 nm to about 50 nm).

Conditioning Agent

The compositions of the present invention may contain a conditioning agent selected from humectants, moisturizers, or skin conditioners. A variety of these materials can be employed and each can be present at a level of from about 0.01% to about 20%, more preferably

from about 0.1% to about 10%, and still more preferably from about 0.5% to about 7% by weight of the composition. These materials include, but are not limited to, guanidine; urea; glycolic acid and glycolate salts (e.g. ammonium and quaternary alkyl ammonium); salicylic acid; lactic acid and lactate salts (e.g., ammonium and quaternary alkyl ammonium); aloe vera in any of its variety of forms (e.g., aloe vera gel); polyethylene glycols; sugars (e.g., melibiose) and starches; sugar and starch derivatives (e.g., alkoxylated glucose, fructose, glucosamine); hyaluronic acid; lactamide monoethanolamine; acetamide monoethanolamine; panthenol; allantoin; and mixtures thereof. Also useful herein are the propoxylated glycerols described in U. S. Patent No. 4,976,953, to Orr et al, issued December 11, 1990.

Also useful are various C_1-C_{30} monoesters and polyesters of sugars and related materials. These esters are derived from a sugar or polyol moiety and one or more carboxylic acid moieties. Such ester materials are further described in, U. S. Patent No. 2,831,854, U. S. Patent No. 4,005,196, to Jandacek, issued January 25, 1977; U. S. Patent No. 4,005,195, to Jandacek, issued January 25, 1977, U. S. Patent No. 5,306,516, to Letton et al, issued April 26, 1994; U. S. Patent No. 5,306,515, to Letton et al, issued April 26, 1994; U. S. Patent No. 5,305,514, to Letton et al, issued April 26, 1994; U. S. Patent No. 4,797,300, to Jandacek et al, issued January 10, 1989; U. S. Patent No. 3,963,699, to Rizzi et al, issued June 15, 1976; U. S. Patent No. 4,518,772, to Volpenhein, issued May 21, 1985; and U. S. Patent No. 4,517,360, to Volpenhein, issued May 21, 1985.

When the conditioning agent is an emollient it is preferably selected from hydrocarbons, fatty acids, fatty alcohols and esters. Isononyl isononanoate is the most preferred hydrocarbon type of emollient conditioning agent. Other hydrocarbons that may be employed include mineral oil, polyolefins such as polydecene, and paraffins such as isohexadecane (e.g. Permethyl 99 Registered TM and Permethyl 101 Registered TM).

Preferably, the conditioning agent is selected from urea, guanidine, sucrose polyester, panthenol, dexpanthenol, allantoin, and combinations thereof.

Other Optional Ingredients

A variety of additional ingredients can be incorporated into the compositions of the present invention. Nonlimiting examples of these additional ingredients include; colorants, dyes, pigments; agents suitable for aesthetic purposes such as essential oils, fragrances, skin sensates, opacifiers, aromatic compounds (e.g., clove oil, menthol, camphor, eucalyptus oil, and eugenol); preservatives (e.g. alkyl esters of para-hydroxybenzoic acid, hydantoin derivatives such as 1,3-

bis(hydroxymethyl)-5,5-dimthylhydantoin, propionate salts, and a variety of quaternary ammonium compounds such as benzalkonium chloride, quaternium 15 [Dowicil 200], benzethonium Chloride, and methylbenzethonium chloride). Particularly preferred preservatives are disodium EDTA, phenoxyethanol, methyl paraben, propyl paraben, imidazolidinyl urea (commercially available as Germall 1157), sodium dehydroacetate and benzyl alcohol.

Testing Methodology

a) Tensile Stress Evaluation

The tensile stress level of a given solvent is a direct indicator of the tackiness of the solvent. The tacky solvents for use herein have a tensile stress level greater than that of petrolatum. Any method known in the art to determine tensile stress can be used to determine the tensile strength of the solvent. An example test method for determining the level of tensile stress is disclosed in Journal Seifen, Ole, Fette, Wache, 118 (1992) 1001, by Zeidle, herein incorporated by reference. This method requires determining the level of tensile stres in mN/cm by the use of a force transducer to measure the amount of adhesion of the tested material.

b) Sensory Tackiness Evaluation

The sensory tactile perception rating is determined by a testing methodology based on the Spectrum Descriptive Analysis method disclosed in "Sensory Evaluation Techniques:, 3rd edition by Meigaard, Civille, and Carr, CRC Press 1999. The method used herein is performed as follows:

1) A set of 10 human graders are trained on evaluating products using the following defined protocol. The graders are instructed to grade tackiness on a scale of 1 - 10. This grade is determined by comparing the tackiness of the test product versus a set of three standard products having preestablished tackiness ratings. The standard control products are Petroleum jelly as the high tack reference (score = 7.5), Avon Moisture Therapy for hands as the moderate tack reference (score 4.5) and Estee Lauder Fruition extra as the low tack reference (score = 0.5).

2) During the test, 0.15 grams of the product to be tested are dispensed and applied by each of the ten graders to one cheek of the grader's face.

3) After 15 minutes of the product being on the skin, the fingers of the grader are pressed against the cheek using the flat portion of the fingers and using moderate pressure.

4) Each trained grader then assesses the tackiness rating by evaluating how easily the fingers are released from the cheek skin in comparison with the standard control product results.

5) The sensory tactile perception rating is then calculated by averaging the scores of each of the ten graders for that particular composition.

The combination of the tacky solvent and the solvent soluble skin care active used herein have a sensory tactile perception rating of greater than 4.5 and the topical skin care composition has a sensory tactile perception rating of less than 4.5. Preferably, the topical skin care composition has a sensory tactile perception rating of less than 3.0, more preferably less than 1.0.

Composition Preparation

The compositions useful for the methods of the present invention are generally prepared by conventional methods such as are known in the art of making topical compositions. Such methods typically involve mixing of the ingredients in one or more steps to a relatively uniform state, with or without heating, cooling, application of vacuum, and the like.

The topical compositions of the present invention may be formulated into a facial skin cosmetic, eye cosmetic, lip cosmetic, scalp hair styling aid, facial hair styling aid, moisturizer, wrinkle soothing serum, lotion, mascara, skin facial mask, skin lotion, skin cream, skin gel, eye gel, eye cream, lip gel, lip cream, cosmetic, foundation, or any other commonly known skin product or treatment.

Methods of Use

The compositions of the present invention are useful for regulating the condition of skin and/or hair while having good aesthetics. Regulating the condition of skin includes reducing the appearance of fine lines and/or wrinkles on the skin, reducing the appearance of eye bags and dark circles under the eys, sagging skin, scars/marks, dimples, pores, stretch marks, roughness, skin surface blemishes, frown lines, expression lines, rhytides, blemishes, photodamage, crevices, and/or unevenness.

Regulation of the keratinous tissue conditions of the skin with such actives in combination with the tacky solvent soluble active, and improved delivery system can include prophylactic and therapeutic regulation. For example, such regulating methods are directed to thickening keratinous tissue (i.e., building the epidermis and/or dermis layers of the skin and where applicable the keratinous layers of the nail and hair shaft) and preventing and/or retarding atrophy of mammalian skin, preventing and/or retarding the appearance of spider vessels and/or red blotchiness on mammalian skin, preventing and/or retarding the appearance of dark circles under the eye of a mammal, preventing and/or retarding sallowness of mammalian skin,

preventing and/or retarding sagging of mammalian skin, softening and/or smoothing lips, hair and nails of a mammal, preventing and/or relieving itch of mammalian skin, regulating skin texture (e.g. wrinkles and fine lines), and improving skin color (e.g. redness, freckles).

In a preferred embodiment the composition is chronically applied to the skin. By "chronic topical application" is meant continued topical application of the composition over an extended period during the subject's lifetime, preferably for a period of at least about one week, more preferably for a period of at least about one month, even more preferably for at least about three months, even more preferably for at least about six months, and more preferably still for at least about one year. While benefits are obtainable after various maximum periods of use (e.g., five, ten or twenty years), it is preferred that chronic application continue throughout the subject's lifetime. Typically applications would be on the order of about once per day over such extended periods, however application rates can vary from about once per week up to about three times per day or more.

A wide range of quantities of the compositions of the present invention can be employed to provide a skin appearance and/or feel benefit. Quantities of the present compositions which are typically applied per application are, in mg composition/cm^2 skin, from about 0.1 mg/cm^2 to about 10 mg/cm^2. A particularly useful application amount is about 1 mg/cm^2 to about 2 mg/cm^2.

Modifying and/or regulating skin appearance, feel, and/or condition is preferably practiced by applying a composition in the form of a skin lotion, cream, gel, foam, ointment, paste, emulsion, spray, conditioner, tonic, cosmetic, lipstick, foundation, nail polish, after-shave, or the like which is preferably intended to be left on the skin or other keratin structure for some esthetic, prophylactic, therapeutic or other benefit (i.e., a "leave-on" composition). After applying the composition to the skin, it is preferably left on the skin for a period of at least about 15 minutes, more preferably at least about 30 minutes, even more preferably at least about 1 hour, still more preferably for at least several hours, e.g., up to about 12 hours. Any part of the external portion of the face, hair, and/or nails can be treated, e.g., face, lips, under-eye area, eyelids, scalp, neck, torso, arms, hands, legs, feet, fingernails, toenails, scalp hair, eyelashes, eyebrows, etc. The composition can be applied with the fingers or with an implement or device (e.g., pad, cotton ball, applicator pen, spray applicator, and the like).

Another approach to ensure a continuous exposure of the skin to at least a minimum level of the composition is to apply the compound by use of a patch applied, e.g., to the face. Such an

approach is particularly useful for problem skin areas needing more intensive treatment (e.g., facial crows feet area, frown lines, under eye area, and the like). The patch can be occlusive, semi-occlusive or non-occlusive and can be adhesive or non-adhesive. The composition can be contained within the patch or be applied to the skin prior to application of the patch. The patch can also include additional actives such as chemical initiators for exothermic reactions such as those described in U.S. Patents numbered 5,821,250, 5,981,547, and 5,972,957 to Wu, et al. The patch is preferably left on the skin for a period of at least about 5 minutes, more preferably at least about 15 minutes, more preferably still at least about 30 minutes, even more preferably at least about 1 hour, still more preferably at night as a form of night therapy.

Examples

The following examples further describe and demonstrate embodiments within the scope of the present invention. The examples are given solely for the purpose of illustration and are not to be construed as limitations of the present invention, as many variations thereof are possible without departing from the spirit and scope of the invention.

Examples 1 - 7

Water-in-Silicone Skin Cream

Water in silicone skin creams are prepared by conventional methods from the following components.

	Ingredient	1	2	3	4
PHASE A:	Water U.S.P.	25.55	14.25	25.25	19.45
	Disodium EDTA	0.10	0.10	0.10	0.10
	Methyl Paraben	0.10	0.10	0.10	0.10
	Propyl Paraben	0.10	0.10	0.10	0.10
	Niacinamide	7.50		7.5	5.0
	Dexpanthenol	1.0	0.50	1.0	1.0
	Magnesium Ascorbyl Phosphate		10		
	Allantoin	0.2	0.2	0.2	0.2
	Benzyl Alcohol	0.25	0.25	0.25	0.25
	Glycerin	15		20	10
	Butylene Glycol		10		
	Terephthalylidene dicamphor sulfonic acid [1]				
	Palmitoyl Lys Thr Thr Lys Ser [2]			0.0003	

PHASE B:	Dow Corning 9040 [3]	15	30		18
	KSG -21 [4]	8.0		15	18
	Cyclomethicone	25	17	30	18
	Dimethicone Copolyol (Dow Corning 5225C)		3		
	Vitamn E Acetate	0.5	0.5	0.5	0.5
	Titanium Dioxide GLW75CAP-MP [5]	0.50	0.50		
	Fragrance	0.2			0.2
	Farnesol				5
	(-)-alpha Bisabolol	1	0.5		1
	Phytantriol		5		
	Parsol 1789 [6]				
	Isopropyl Palmitate				
	Salicylic Acid				
	PPG-15-Stearyl Ether				
	Tospearl 145		1		1
PHASE C	Finsolv TN				2.0
	Retinol 50 P				0.1
	Retinyl Propionate				

	Ingredient	5	6	7
PHASE A:	Water U.S.P.	35.55	56.05	32.25
	Disodium EDTA	0.10	0.10	0.10
	Methyl Paraben	0.10	0.10	0.10
	Propyl Paraben	0.10	0.10	0.10
	Niacinamide	3.5	10	5.0
	Dexpanthenol	0.5	1.0	0.50
	Magnesium Ascorbyl Phosphate			
	Allantoin	0.2	0.2	0.2
	Benzyl Alcohol	0.25	0.25	0.25
	Glycerin	7	10	15.
	Butylene Glycol			
	Terephthalylidene dicamphor sulfonic acid [1]			5.0
	Palmitoyl Lys Thr Thr Lys Ser [2]			
PHASE B:	Dow Corning 9040 [3]	10		10

	KSG -21 [4]	7	2	10
	Cyclomethicone	20	10	20
	Dimethicone Copolyol (Dow Corning 5225C)			
	Vitamn E Acetate	0.5	0.5	0.5
	Titanium Dioxide GLW75CAP-MP [5]			
	Fragrance		0.2	
	Farnesol			
	(-)-alpha Bisabolol			
	Phytantriol	3		
	Parsol 1789 [6]	3.0		
	Isopropyl Palmitate	7.0		
	Salicylic Acid		1.5	
	PPG-15-Stearyl Ether		8	
	Tospearl 145			1
PHASE C	Finsolv TN	2.0		
	Retinol 50 P			
	Retinyl Propionate	0.2		

[1] Can be obtained from Chimex as Mexoryl SX

[2] Peptide can be obtained from Sederma

[3] 12% Dimethicone/Vinyl Dimethicone crosspolymer in cyclomethicone from Dow Corning

[4] Available from Shin-Etsu; 25% Dimethicone/Copolyol Crosspolymer in dimethicone

[5] Titanium Dioxide GLW75CAP-MP can be obtained from KOBO

[6] Parsol 1789 can be obtained from Roche

In separate suitable containers are added the ingredients of Phase A and Phase B and both Phases are mixed using a suitable mixer (e.g., Tekmar model RW20DZM) equipped with a propeller blade. When both Phases are homogenous, slowly add Phase A to Phase B while mixing Phase B with propeller blade. Maintain mixing until batch is uniform. Mill emulsion using a suitable mill (Tekmar T25) for several minutes to insure uniformity. Pour product into suitable containers.

Examples 8 - 15

Oil-in-Water Skin Lotion

An oil in water skin lotion is prepared by conventional methods from the following components.

	Ingredient	Ex 8	Ex. 9	Ex. 10	Ex. 11
PHASE A	Water U.S.P.	QS to 100	QS to 100	QS to 100	QS to 100
	Disodium EDTA	0.1	0.1	0.1	0.1
	Allantoin	0.2	0.2	0.2	0.2
	Glycerin	15		10	20
	Butylene Glycol		10		
	Methyl Paraben	0.2	0.2	0.2	0.2
	Niacinamide	7.5		5	10
	Magnesium Ascorbyl Phosphate		10		
	2-Phenylbenzimidazole-5-sulphonic acid				
	Triethanolamine				
Phase B	Polysorbate 40	2	2	2	3
	Glyceryl Monostearate	2	2	2	2
	Cetyl Alcohol	1	1	1	1
	Stearyl Alcohol	1	1	1	1
	Farnesol				5
	Phytantriol				
	Salicylic Acid				
	Titanium Dioxide SAT-T-CR50 [1]				
	PPG-15 Stearyl Ether				
	Vitamin E Acetate	0.5	0.5	.5	.5
	Permethyl 101 A	5	5	3	3
	Parsol 1789				
	Octocrylene				
	Octyl Salicylate				
Phase C	Sepigel 305 [5]	1	1	1	1
Phase D	Dow Corning 9040 [4]	8		4	7
	KSG-21 [3]		7	4	
	Dow Corning 245	2	3	4	2
Phase E	Retinyl Propionate				
	Finsolv TN				
	Fragrance	0.2	0.2		

	Ingredient	Ex. 12	Ex.13	Ex. 14	Ex. 15
PHASE A	Water U.S.P.	QS to 100	QS to 100	QS to 100	QS to 100
	Disodium EDTA	0.1	0.1	0.1	0.1
	Allantoin	0.2	0.2	0.2	0.2
	Glycerin	15	10	10	15
	Butylene Glycol			5	
	Methyl Paraben	0.2	0.2	0.2	0.2
	Niacinamide	7.5	5		7.5
	Magnesium Ascorbyl Phosphate			5	
	2-Phenylbenzimidazole-5-sulphonic acid				4
	Triethanolamine				2
Phase B	Polysorbate 40	3	3	2	3
	Glyceryl Monostearate	2	2	2	2
	Cetyl Alcohol	1	1	1	1
	Stearyl Alcohol	1	1	1	1
	Farnesol				
	Phytantriol	5			
	Salicylic Acid			1.5	
	Titanium Dioxide SAT-T-CR50 [1]			0.5	
	PPG-15 Stearyl Ether			8	
	Vitamin E Acetate				
	Permethyl 101 A				3
	Parsol 1789				2
	Octocrylene				1.5
	Octyl Salicylate				5
Phase C	Sepigel 305 [5]	1	1	1	1
Phase D	Dow Corning 9040 [4]		7		8
	KSG-21 [3]	5		4	
	Dow Corning 245	3		2	3
Phase E	Retinyl Propionate		0.2		
	Finsolv TN		2		
	Fragrance				

[1] Available from US Cosmetics

[2] Available from Roche

[3] Available from Shin-Etsu; 25% Dimethicone/Copolyol Crosspolymer in dimethicone

[4] 12% Dimethicone/Vinyl Dimethicone crosspolymer in cyclomethicone

[5] Sepigel 305 can be purchased from Seppic and is Polyacrylamide and C13-14 isoparaffin and Laureth-7

Blend the A phase components with a suitable mixer (e.g., Tekmar model RW20DZM), heating while stirring to a temperature of 70-80°C. Separately, blend the B phase components with a suitable mixer and heat to 70 - 75°C and maintain while mixing. Phase B is added to Phase A while mixing well to emulsify. When emulsion is at approx. 60°C, Phase C is added while continuing to mix emulsion At approx. 50°C, Phase D is added to the emulsion and mixing continued. At approx. 40°C, Phases E is added to the emulsion The emulsion is then milled using a suitable mill (Tekmar T-25) for approx. 5 minutes resulting in an uniform product.

Examples 16 - 18

Anhydrous Skin Cream

An anhydrous skin cream is prepared by conventional methods from the following components.

Ingredient	Ex 16	Ex. 17	Ex. 18
Butylene Glycol	5	5	5
Glycerin	15	15	15
MOLSIV Adsorbent 3A [1]	40	30	40
Cyclomethicone	15	15	15
Dow Corning 9040 [2]	10		5
KSG-21 [3]		10	5
Polyethylene Glycol	5	15	5
Kaolin [4]	10	10	10

[1] MOLSIV Adsorbent 3A is a zeolite available from UOP

[2] Available from Shin-Etsu; 25% Dimethicone/Copolyol Crosspolymer in dimethicone

[3] 12% Dimethicone/Vinyl Dimethicone crosspolymer in cyclomethicone

[4] Kaolin is a hydrated aluminium silicate available from Whittaker Clark & Daniels

Blend all the components with a suitable mixer (e.g., Tekmar model RW20DZM) until homogeneous.

WHAT IS CLAIMED IS:

1. A topical skin care composition having improved aesthetics comprising:

a) from 0.0001% to 40%, by weight of the composition, of a skin care active, preferably niacinamide, wherein the skin care active is soluble in a tacky solvent;

b) a dermatologically acceptable delivery system which comprises:

i) from 1% to 60%, by weight of the composition, of a tacky solvent, preferably glycerin;

ii) from 0.1% to 30% of a silicone elastomer;

iii) from 1% to 80% of a carrier for the elastomer;

wherein the mixture of the tacky solvent and the skin care active has a sensory tactile perception rating of greater than 4.5; and wherein the topical skin care composition has a sensory tactile perception rating of less than 4.5, preferably less than 1.0.

2. A composition according to Claim 1 wherein the ratio of the tacky solvent to the skin care active is from 3:2 to 2:1.

3. A composition according to Claim 1 or 2, wherein the silicone elastomer is selected from the group consisting of a dimethicone copolyol crosspolymer and dimethicone mixture, dimethicone/vinyl dimethicone crosspolymers, and mixtures thereof.

4. A composition according to any one of the preceding claims wherein the composition further comprises from 1% to 95% water.

5. A composition according to any one of the preceding claims wherein the composition further comprises a conditioning agent selected from the group consisting of exfoliants, emollients, and mixtures thereof.

6. A composition according to any one of the preceding claims, wherein the composition further comprises a colorant selected from the group consisting of inorganic pigments, organic pigments, lakes, dyes, toners, and mixtures thereof.

7. A topical composition having improved skin feel comprising:

a) from 5% to 20% of niacinamide;

b) from 7.5% to 45% of glycerin;

c) from 2% to 10% of a silicone elastomer;

d) from 5% to 40% of a carrier for the elastomer;

wherein the ratio of glycerin to niacinamide is at least 3:2.

8. A composition according to any one of the preceding claims wherein the composition further comprises from 0.1% to 50% of an additional skin care active selected from the group consisting of farnesol, salicylic acid, pentapeptides, vitamin E derivatives, and mixtures thereof.

9. The use of a composition according to any of the preceding claims for the manufacture of a medicament for regulating the condition of skin.

10. The use of a composition according to any of claims 1 to 8 for the manufacture of a medicament for regulating the appearance of fine lines and wrinkles on skin.